OPTN Ad Hoc Multi-Organ Transplantation Committee
Meeting Summary
August 8, 2024
In-Person Meeting, Richmond, VA

Lisa Stocks, RN, MSN, FNP, Chair
Zoe Stewart Lewis, MD, PhD, MPH, FACS, Chair

Introduction

The Ad Hoc Multi-Organ Transplantation (MOT) Committee, the Committee, met in-person on 08/08/2024 in Richmond, VA, to discuss the following agenda items:

1. Monitoring Report on Safety Net for Heart-Kidney and Lung-Kidney Allocation
2. Data Request: Modeling Results
3. Data Request: Descriptive Data Results
4. Values Prioritization Exercise: Results
5. Review MOT Allocation Scheme Variations
6. Revise Draft MOT Allocation Scheme
7. Map future development of Draft MOT Allocation Scheme

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

1. Monitoring Report on Safety Net for Heart-Kidney and Lung-Kidney Allocation

OPTN contractor staff provided an overview of the Monitoring Report on Safety Net for Heart-Kidney and Lung-Kidney Allocation.

Summary of Presentation:

The report focuses on the 6-month period following implementation of policy to establish eligibility criteria for simultaneous heart-kidney (SHK) and simultaneous lung-kidney allocation (SLuK) and to create a safety net for kidney after heart and kidney after lung allocation.

Following the policy implementation, multi-organ registrations decreased as a proportion of all heart or lung registrations. However, more multi-organ registrations met SHK eligibility criteria post-policy, while SLuK eligibility remained similar. Chronic kidney disease (CKD) was the main reason for the increase in registrations meeting SHK eligibility. Deceased donor transplant was the primary reason for waiting list removal in both eras.

Although multi-organ transplants decreased overall, those meeting SHK or SLuK eligibility criteria increased post-policy. Most candidates eligible for SHK or SLuK transplants qualified through CKD sub-criteria. Pre- and post-policy, heart statuses for SHK recipients were similar, while SLuK recipients tended to have higher Composite Allocation Scores (CAS) post-policy. Delayed graft function rates for SHK remained similar, and no SLuK recipients experienced delayed graft function post-policy.

In relation to the safety net, the number of kidney-after-heart safety net registrations waiting at the end of each month increased over time. More deceased donor transplants occurred post-implementation for both kidney-after-heart and kidney-after-lung registrations. All kidney safety net recipients were eligible at transplant time, with most avoiding delayed kidney graft function.

Summary of Discussion:

> **The Committee did not make any decisions.**

The Committee noted that the policy may be flattening the increase in multi-organ kidney transplants. Members expressed some concerns, including on the increase in eligible patients after the policy change and recipients receiving sequence B kidneys through the safety net, when sequence C or D kidneys may be more appropriate. A member requested data on the kidney donor profile index (KDPI) of kidneys allocated with primary organs, hypothesizing that higher KDPI kidneys may be allocated with primary organs, and lower KDPI kidneys through safety net policies. Members noted the rise in SHK transplants, possibly due to the inclusion of Status 4 and 5 heart patients. They noted that heart allocation leans towards sicker patients (Status 1 and 2), who are more likely to develop kidney injury.

Members agreed that the 6-month monitoring period may not provide enough data to evaluate the policy and identify potential refinements. They emphasized the importance of ongoing monitoring to inform potential enhancements. The Chair suggested considering enhancements once the Committee reviews the 1-year monitoring report.

Next Steps:

The Committee will consider potential enhancements to the safety net policies after reviewing the 1-year monitoring report.

2. **Data Request: Modeling Results**

Scientific Registry of Transplant Recipients (SRTR) staff presented results of an inferential data request.

Presentation summary:

The goal of the data request was to inform the Committee's multi-organ allocation project by estimating the risk of death on the waiting list compared with longevity of the patient and graft post-transplant. The models were time-to-event (Cox proportional hazards) models. For waitlist survival, the outcome was death (including after removal for reasons other than transplant). For post-transplant survival, the outcome was all-cause graft failure. Timeframes for waitlist survival and post-transplant survival were 1 year. The analysis included the following variables: allocation-relevant status and multi-organ indicators (always included) and covariates identified as relevant in SRTR program-specific reports (included where relevant). The report included estimates of waitlist survival and post-transplant survival. Data on time to offer will be provided later in the fall.

Summary of discussion:

> **The Committee did not make any decisions.**

Members spent time discussing the data on heart (Classification 1)-kidney transplants, as an example. The total number of patients on the waitlist was 188. Estimated waitlist survival was about 50%, meaning about 94 patients would be expected to survive one year on the waitlist. There were 589 transplants. Estimated post-transplant survival (of both grafts) was about 90%.

Members highlighted that heart (Classification 1)-liver patients seem to have higher waitlist survival than heart-kidney patients. A member suggested that this may be due to the MELD (Model for End-Stage Liver Disease) score incorporating kidney function, resulting in a subset of liver patients whose MELD is driven by kidney issues or dialysis.

Regarding the data for liver patients, members noted the small number of Classification 1 liver patients and considered the data on MELD > 37 patients to be more reliable and informative.

SRTR staff noted that the analysis can be further developed depending on the Committee's needs as it continues to refine the draft allocation scheme.

Next Steps:

None were discussed.

3. Data Request: Descriptive Data Results

OPTN contractor staff presented the results of the descriptive data request on OPTN waitlist outcomes and median time to transplant.

Summary of Presentation:

For OPTN waitlist outcomes, data was from the period July 1st, 2021 to December 31st, 2023. Removal reasons included transplanted, death, too sick, candidate condition improved, and other (e.g., transfers, unable to contact, etc.). Waitlist removal analysis was based on primary organ registration. The presentation included tables showing breakdowns of removal reason for heart multi-organ transplants (based on heart registration), lung multi-organ transplants (based on lung registrations), liver multi-organ transplants (based on liver registrations), and kidney alone and kidney-pancreas transplants (based on kidney registrations).

For median time to transplant, data was from the period July 1st, 2021 to December 31st, 2023. Waiting time for multi-organ recipients began when the candidate was registered for the second organ in the combination. For multivisceral transplants, waiting time started when listed for both liver and intestine. Staff noted that calculating median waiting time with a cohort of transplant recipients may be biased as it does not consider candidates still waiting for transplant that may accrue longer waiting times.

The presentation included charts showing breakdowns of median time to transplant for heart multi-organ transplants (based on heart registration), lung multi-organ transplants (based on lung registrations), liver multi-organ transplants (based on liver registrations), and kidney alone and kidney-pancreas transplants (based on kidney registrations).

Summary of discussion:

The Committee did not make any decisions.

Members noted the limitations of the time to transplant analysis and that the upcoming time to next offer analysis may be more informative.

Members noted the long wait times for multivisceral transplants. They further noted that there are very few programs with enough volume to have ASTS certified training programs for intestine/multi-visceral transplants. A member suggested that high quality pancreata and intestines are needed to ensure successful multivisceral transplants.

Some members suggest prioritizing these rare mulstivisceral patients over other transplants, given their small numbers and unique needs. Some cautioned against putting multivisceral patients ahead of all others, especially Status 1 heart or Status 1A liver patients. Members noted that since policy changes implemented last year, multivisceral patients receive high priority. This does not include pancreata, potentially disadvantaging multivisceral patients who also need a pancreas.

A member noted the complexity of balancing the needs of medically urgent candidates, potential organ nonuse, and the need for a streamlined and efficient process. Another member noted that organ procurement organizations (OPOs) are concerned about organ nonuse, as they are evaluated on this metric.

Next Steps:

None were discussed.

4. Values Prioritization Exercise: Results

OPTN contractor staff presented results of the Values Prioritization Exercise (VPE).

Summary of Presentation:

The goal of the VPE was to help the Committee identify and/or build clinical consensus on organ allocation priorities across match runs, especially where data is limited. Eighteen past and current Committee members completed the VPE. Two additional members partially completed the VPE. Participants were asked to enter background information including their affiliation to transplant and organ-specific expertise.

The VPE comprised 16 candidate comparisons and some comparisons included follow up questions. Participants were asked to determine which candidate should receive priority, assuming the donor was a 30-year-old brain dead donor with a KDPI of 0-20% with all organs available to donate (heart, both lungs, liver, intestine, pancreas, and both kidneys). Participants were also asked to identify their primary reason for prioritizing candidates (access to transplant, distance, post-transplant survival, potential organ non-use, waitlist mortality concerns, or none of the above). They were also asked to rate their confidence in their selections on a scale of 1 (not at all confident) to 5 (extremely confident).

An overview of the results is provided below, showing comparisons and votes for prioritization:

- Adult Liver Status 1A Candidate (11) compared to Adult Heart Status 1 Candidate (7)
- Heart Status 1 Candidate (9) compared to Pediatric Liver Status 1B Candidate (9)
- Pediatric Heart Status 1A Candidate (16) compared to Pediatric Liver Status 1B Candidate (2)
- Adult Liver Status 1A Candidate (16) compared to Adult Heart Status 2 Candidate (2)
- Pediatric Liver Status 1B Candidate (12) compared to Adult Heart Status 2 Candidate (6)
- Adult Heart Status 1 Candidate (16) compared to Lung CAS > 25 Candidate (2)
- Adult Heart Status 2 (11) compared to Lung CAS > 25 Candidate (7)
- Adult Liver Status 1A Candidate (14) compared to Lung CAS > 25 Candidate (4)
- Pediatric Liver Status 1B Candidate (16) compared to Lung CAS > 25 Candidate (2)
- Liver MELD > 37 Candidate (16) compared to Intestine Status 1 Candidate (2)
- Intestine Status 1 Candidate (12) compared to Kidney-Pancreas Classification 1 and 2 Candidates (6)
- Liver MELD > 37 Candidate (12) compared to Kidney-Pancreas Classification 1 and 2 Candidates (6)
- Kidney-Pancreas Classification 1 or 2 Candidates (10) compared to Kidney Classification 1 and 2 Candidates (8)
- Kidney Classification 1 or 2 Candidates (11) compared to Kidney-Pancreas Classification 3 Candidate (7)

- Kidney Classification 7 Candidate (12) compared to Kidney-Pancreas Classification 3 Candidate (7)

- Adult Heart Status 3 Candidate (12) compared to Kidney Classification 5 (6)

- Kidney Classification 6 Candidate (11) compared to Heart Status 3 Candidate (7)

- Pediatric Heart Status 1B Candidate (15) compared to Kidney Classification 6 Candidate (3)

- Kidney Classification 7 Candidate (12) compared to Adult Heart Status 3 Candidate (6)

Staff also presented on the use of VPEs as part of development of continuous distribution systems for lung, kidney, pancreas, liver, and heart. They discussed attributes (medical urgency, patient access, candidate biology, post-transplant survival, and placement efficiency), and the ranking of those attributes in each of the organ-specific VPEs. They noted that patient access is a broad category with differing definitions, including pediatric, prior living donor, waiting time, and safety net.

Summary of discussion:

> **The Committee did not make any decisions.**

Members noted the ongoing effort to move towards continuous distribution and create a consistent framework across organs. The transition period, where some organs use classifications and others use points-based systems, may be the most complicated. They noted ongoing discussions across Committees about fitting MOT allocation into the new continuous distribution framework.

Members noted that VPEs as part of continuous distribution were open to the public, with higher participation from patients and the public compared to regular policy proposals. Respondents were asked to identify their affiliation to transplant, including patients, general public, OPOs, and laboratories and results were population-adjusted. Members identified key priorities in allocation from organ-specific VPEs. Medical urgency and patient access appeared to be the most important factors. Post-transplant survival seems to have received lower priority in most cases, except for lung allocation, where it accounts for about 50%. A member advised that the lung CAS uses five-year post-transplant survival. The Lung Committee opted for five-year survival in the final score, as one-year survival wasn't seen as impactful for decision-making. For heart allocation in CD, post-transplant survival will likely not be an attribute, despite being included in the Heart VPE. The Heart Committee decided against including this attribute, and it received low priority in the Heart VPE.

Members noted that patient access was not specifically defined in the MOT Committee's VPE, though the comments indicated that CPRA and pediatric status were taken into account.

Next Steps:

None were discussed.

5. Review MOT Allocation Scheme Variations

OPTN contractor staff presented variations of the MOT allocation scheme, based on waitlist survival data and the VPE results.

Summary of Presentation:

The following variations were presented:

- Initial draft MOT allocation scheme
- Allocation scheme based on waitlist survival

- Waitlist mortality 1-year survival mean and post-transplant 1-year survival mean are based on single- and multi-organ candidates in the classification
- Allocation scheme based on VPE results
- Allocation scheme based on waitlist mortality and VPE results (option 1)
  - Primarily influenced by waitlist mortality
  - Considers VPE results as waitlist survival mean estimates were similar
- Allocation scheme based on waitlist mortality and VPE results (option 2)
  - Primarily influenced by VPE and adjusted based on potential efficiency barriers
  - Except for Liver Status 1A/B, the option prioritizes thoracic candidates based on their waitlist mortality survival mean estimates prior to abdominal candidates

Summary of discussion:

The Committee did not make any decisions.

The Committee selected the allocation scheme based on VPE results as the basis for its discussion on revising the scheme, described in agenda item 6, below.

Members clarified that the proposed scheme covers both single and multi-organ candidates. They discussed how the scheme would direct OPOs to work through different match runs and allocate to both single- and multi-organ candidates on the match runs.

Members emphasized the importance of efficiency and getting user feedback on the practicalities of the scheme. Another member shared a transplant center's perspective that it is difficult to understand why highly medically urgent patients are bypassed for lower sequence multi-organ candidates. Members advised that it can be difficult for OPOs navigating allocation priorities across match runs. They noted that some OPOs rely on experienced case staff to interpret policies and create allocation plans. They noted differences in how OPOs currently allocate organs, which may complicate standardization. Members agreed that one of the benefits of the proposed policy would be consistent allocation practices across OPOs.

Members confirmed the need for IT solutions to help streamline allocation in accordance with policy. A member suggested dashboard or program that could assist OPOs in navigating complex allocation policies.

Next Steps:

The Committee will revise the draft MOT allocation scheme, which assumes that the donor is a 30-year-old brain dead donor with all organs available and KDPI of 0-20%. Subsequently, the Committee will consider additional algorithms based on different donor characteristics.

6. Revise Draft MOT Allocation Scheme

The Committee revised the draft MOT allocation scheme. Its starting point was the variation based on the VPE results.

Summary of discussion:

The Committee revised the draft MOT allocation scheme:

- **Increased priority of Liver Classifications 1-4**
- **Requested that the Lung-MOT Workgroup recommend 2 CAS thresholds for inclusion in the scheme**

- **Increased priority of Kidney Classifications 1-4 (highly sensitized)**
- **Increased priority of Kidney Classification 5 (prior living donors) (Vote: 8 yes; 5 no; 0 abstain)**
- **Increased priority of heart Classifications 5 and 6**
- **Included P/KP Classification 4 in the scheme**
- **Increased priority of P/KP Classifications 3 and 4 (Vote: 9 yes; 4 no; 0 abstain)**

The Chair reviewed several factors that the Committee may wish to consider when deciding upon revisions to the draft MOT allocation scheme, including waitlist survival, access to transplant, post-transplant survival, utility (potential organ non-use), time to next offer, efficiency, equity, and distance.

Members agreed to give Liver Classification 1 the highest priority in the draft scheme. Members also agreed to high priority for Liver Classifications 2-4, based on waitlist survival data and to increase access to transplant for these patients. Members also noted that there are very few highly medically urgent liver patients and that there are no mechanical support devices for them. Liver Classification 1 is followed by Heart Classifications 1 and 2, followed by Liver Statuses 2-4, followed by Heart Classifications 3 and 4.

Members discussed the priority for lung candidates and the current CAS threshold of > 25 for required MOT shares. Members agreed that the allocation scheme should include two lung CAS thresholds, to better stratify priority for lung candidates among other candidates. The Committee requested that the Lung-MOT Workgroup recommend two CAS thresholds for inclusion in the scheme.

The higher lung CAS threshold is followed by Liver Classifications 5-12, based on data showing poor waitlist survival for these patients. Next, is Intestine Classifications 1-4. Members noted that this group is small in number, with high need, and they can wait a long time. The Committee agreed that the lower CAS threshold should be placed below Intestine Classifications 1-4.

The Committee discussed highly sensitized kidney patients (Classifications 1-4), who receive offers exceedingly rarely. Members considered increasing the priority of these candidates, to increase their access to transplant. The Committee agreed to place Kidney Classifications 1-4 below the higher lung CAS threshold and above Liver Classifications 5-12.

Members discussed prior living donors (Kidney Classification 5) and considered increasing their priority to honor the gift of life and supporting living donation. Members expressed differing views on the appropriate level of priority as compared to highly medically urgent candidates. Members expressed concern that kidney-pancreas candidates were receiving lower priority and that the prioritization of kidney-pancreas candidates compared to prior living donor kidney candidates and pediatric kidney candidates was not part of the VPE. A member made a motion to place Kidney Classification 5 (prior living donors) directly below Kidney Classifications 1-4 (highly sensitized). The Committee voted yes: 8; no: 5; and abstain: 0, meaning that the motion passed.

Members discussed the appropriate priority for Heart Classifications 5 and 6. In the VPE exercise, members allocated different levels of prioritization to Adult Status 3 patients and Pediatric Status 1B patients, who all fall within Classifications 5 and 6. The Committee agreed to increased priority of Heart Classifications 5 and 6 above Pancreas/Kidney-Pancreas Classification 3, because pancreata are not typically shared nationally.

Members agreed that Pancreas/Kidney-Pancreas Classification 4 should be included in the scheme. They considered placing Pancreas/Kidney-Pancreas Classifications 3 and 4 above Kidney Classification 6 (pediatric) and 7 (medically urgent) to promote access to transplant and organ utilization. A member made a motion to place Pancreas/Kidney-Pancreas Classifications 3 and 4 above kidney Classifications 6 (pediatric) and 7 (medically urgent). The Committee voted yes: 9 ; no: 4; 0 abstain.

The Chair asked whether it would be possible to model what match runs would look like based on the revised scheme. Staff advised that current simulators cannot model across match runs, but that it would be possible to estimate the number of offers that would be required in each classification based on historic data. A member asked whether it is possible to estimate how this scheme would differ from current allocation practices, including impacts on kidney-pancreas allocation.

7. Map future development of Draft MOT Allocation Scheme

OPTN Contractor staff presented an overview of the future development of draft MOT allocation scheme.

Summary of Presentation:

Decisions needed for policy proposal:
- Evaluate and consider updates to lung multi-organ policies
- Determine which donors go through the MOT allocation scheme
- Consider how to incorporate current MOT policies
- Clarify OPO action following completion of the MOT scheme
- Clarify OPO action for any donors not subject to the MOT scheme
- Consider IT solutions to support implementation
- Consider mechanisms to monitor compliance
- Finalize policy proposal

Donors going through MOT allocation scheme:
- To date, the MOT Committee has developed the allocation scheme based on a 30-year-old brain dead donor with all organs available and KDPI of 0-20%
- Some organs have different allocation sequences based on donor characteristics, which changes how the classifications are ordered
- Including more donors in MOT required shares would require modifying the MOT allocation scheme to reflect the different allocation sequences
- The Committee may also wish to consider different prioritization orders based on different donor characteristics (e.g. lower vs. higher KDPI)
- If the Committee wishes to cover all donors, it would need to develop up to 16 different variations on its initial scheme

Summary of discussion:

> **The Committee did not make any decisions.**

Members suggested that we add choice of right versus left donor kidney to the workplan, as this may need to be addressed in the policy proposal.

Members expressed interest in developing different schemes based on different donor characteristics, including KDPI and donor age. Others preferred fewer schemes to avoid complexity. Some members suggested that it may be appropriate to exclude certain donor groups from the scheme, such as donors older than 70 and/or donors with very high KDPIs.

Members recognized the need to address other special cases like multi-visceral transplants as part of the overall framework.

<u>Next steps:</u>

- Staff will circulate the revised draft MOT allocation scheme agreed on by the Committee during today's meeting
- Staff will develop variations of the draft MOT allocation scheme based on different donor characteristics

Upcoming Meeting

- August 21, 2024

Attendance

- **Committee Members**
  - Lisa Stocks, Chair
  - Zoe Stewart Lewis, Chair
  - Marie Budev
  - Vincent Casingal
  - Richard Daly
  - Alden Doyle
  - Rachel Engen
  - Jonathan Fridell
  - Shelley Hall
  - Jim Kim
  - Heather Miller
  - Shunji Nagai
  - Oyedolamu Olaitan
  - Sharyn Sawczak
  - Chris Sonnenday
  - Nicole Turgeon
- **HRSA Representatives**
  - Marilyn Levi
  - James Bowman
- **SRTR Staff**
  - Jonathan Miller
  - Katie Audette
- **UNOS Staff**
  - James Alcorn
  - Roger Brown
  - Viktoria Filatova
  - Katrina Gauntt
  - Sarah Langham
  - Sarah Roache
  - Laura Schmitt
  - Kaitlin Swanner
  - Ross Walton
  - Cindy Young