

OPTN Ad Hoc Multi-Organ Transplantation Committee

Meeting Summary

October 30, 2024

In-Person Meeting

Lisa Stocks, RN, MSN, FNP, Chair

Zoe Stewart Lewis, MD, PhD, MPH, FACS, Chair

Introduction

The Ad Hoc Multi-Organ Transplantation (MOT) Committee (Committee) met in-person IN Detroit, MI, on 10/30/2024 to discuss the following agenda items:

1. Expand required simultaneous liver-kidney allocation six-month monitoring
2. Follow up discussion: MOT offers and medical eligibility criteria
3. Liver/Intestine small group report out
4. Pediatric small group report out
5. Lung-MOT work group report out
6. Kidney small group report out
7. Finalize MOT allocation algorithms
8. Laterality small group report out
9. Public comment and feedback questions

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

1. Expand required simultaneous liver-kidney allocation six-month monitoring

OPTN Staff presented the expanded required simultaneous liver-kidney allocation six-month monitoring report.

Data summary:

The Committee's Expand Required Simultaneous Liver-Kidney Allocation policy expanded the geographic threshold for required simultaneous liver-kidney (SLK) offers from 250NM to 500NM. This change sought to improve equity in access for simultaneous liver-kidney transplant candidates. It was not expected to greatly increase liver-kidney transplants or have a large impact on access to kidney-alone or pancreas-kidney transplantation.

The monitoring report compared liver-kidney and kidney-alone candidates ever-waiting or transplanted 6 months before and after policy implementation. The report included several key findings. The number of OPTN waiting list registrations ever-waiting or removed due to death or too sick for kidney-alone and liver-kidney candidates remained consistent. The number of simultaneous liver-kidney transplants remained consistent. The median distance between donor hospital and transplant hospital remained similar for simultaneous liver-kidney recipients. The consistency in the median distance may be attributable to an increase in liver-kidney transplants from DCD donors. Simultaneous liver-kidney recipients were more likely to have a MELD/PELD at transplant of 33 or above. The number of pediatric liver-kidney candidates and recipients decreased. The impact based on OPTN regions varied although by a small magnitude; some regions saw an increase in the volume of simultaneous liver-kidney transplants while some saw a decrease.

Summary of discussion:

The Committee did not make any decisions.

The Chair noted that the 6 month monitoring report confirmed that the policy was having the intended impacts. Another member requested clarification regarding the liver-kidney transplants, asking whether the data included all regular liver transplants, if there was an increase in the overall number of livers, and whether that change affected the overall interpretation. UNOS staff confirmed that they had focused solely on kidneys and had not analyzed liver transplants. Another member expressed disappointment that, despite efforts to improve access for simultaneous liver-kidney (SLK) patients by addressing distance issues, there had been no change in the status of Standard Regional Donor (SRD) listings. Many programs continue to employ the same strategies, using donation after circulatory death (DCD) organs while raising concerns about their outcomes. Finally, a member pointed out that the Normothermic Regional Perfusion (NRP) method helps improve the quality of both kidney and liver organs, which could be beneficial for SLK patients. The Chair noted that further work will be needed to address remaining concerns about SLK transplantation, suggesting that further adjustments could be made after the 1 year monitoring report and/or as part of the Committee's upcoming multi-organ policy proposal.

2. Follow up discussion: MOT offers and medical eligibility criteria

OPTN Staff presented potential options to structure multi-organ offers and options to address eligibility criteria.

Presentation summary:

The goals of the discussion were to develop consensus on which organs can be pulled on each match run and where medical eligibility in current policy could be incorporated or may need to be developed.

- For offers made from the heart match run, hearts could “pull” all other organs and the policy proposal could incorporate existing medical eligibility criteria. These rules could apply to offers covered by an algorithm and those not covered by an algorithm.
- For offers made from the lung match run, lungs could “pull” all other organs and the policy proposal could incorporate existing medical eligibility criteria. These rules could apply to offers covered by an algorithm and those not covered by an algorithm.
- For offers made from the liver match run, livers could “pull” all other organs and the policy proposal could incorporate existing medical eligibility criteria, though criteria would need to be developed for livers pulling hearts and lungs, as this is not addressed in current policy. These rules could apply to offers covered by an algorithm and those not covered by an algorithm.
- For offers made from the intestine, kidney, pancreas, and kidney-pancreas match runs, if the Committee agrees that these abdominal organs should “pull” hearts, lungs, and livers, eligibility criteria would need to be developed. Alternatively, the Committee could determine that abdominal organs only pull other abdominal organs.

Summary of discussion:

The Committee did not make any decisions.

Committee members discussed examples of how the proposed rules would impact allocation as OPOs work through the algorithms. They noted that allocation of organs is usually done in parallel. The Chair noted the importance of the recently implemented Modify Effect of Acceptance Policy, which confirms

that acceptance of an organ takes priority over required multi-organ offers further down the match run. A member noted the complexity of the rules and that strong education and system level guidance would be needed to ensure that OPO users can efficiently work through match runs in accordance with the policy changes, if adopted. A member requested data to help the Committee understand what percentage of offers may not be covered by an algorithm. Members discussed multivisceral offers within the context of the algorithms. They questioned whether MELD scores lower than 37 should be included in the initial draft algorithm. They tended to agree that exception requests for multivisceral candidates could ensure access to transplant in the context of the algorithms, without the need to add additional classifications.

The Committee discussed whether abdominal organs should “pull” other organs. There was general support for intestines pulling all other organs, except for livers. The Committee tended to agree that an exception for livers would be necessary to ensure access to transplant for medically urgent liver candidates. Some members expressed support for kidneys “pulling” all other organs, if this was restricted to high priority kidney classifications and eligibility criteria was developed. Overall, members tended to think that when offering from the kidney, pancreas, and kidney-pancreas match runs, those organs should pull abdominal organs, with the exception of livers. A question about which organs should pull which could be included in the public comment update.

Next steps: The Committee will refine the structure of multi-organ offers and plans to incorporate and/or develop eligibility criteria prior to finalizing the public comment update.

3. Liver/Intestine small group report out

The small group leader presented the recommended algorithm for DCD adult donors with lower KDPI.

Presentation summary:

The classifications are in the same order as the initial draft algorithm, except for liver and liver-intestine classifications. The group reviewed data on multi-organ transplantation numbers and percentages of DCD donors compared to DBD donors. The small group presented two potential algorithms for DCD donors, adjusting the initial draft algorithm based on the different allocation priorities for DCD donors. The Committee decided to proceed with the second option, which included Liver Classifications 1-5 in the same position as in the initial draft algorithm and lower MELD/PELD classifications beyond 250NM at the end of the algorithm.

Discussion was reserved for agenda item 7. Finalize MOT allocation algorithms.

4. Pediatric small group report out

The small group leader and OPTN Contractor staff presented considerations relevant to pediatric multi-organ donors and candidates and the recommended algorithm for pediatric donors.

Presentation summary:

The small group leader presented data on pediatric donors and transplants. The algorithms developed by the Committee cover 99% of pediatric multi-organ transplant donors between July 1, 2021 and December 21, 2023. Pediatric multi-organ transplants constitute a very small percentage (2.11%) of overall multi-organ transplants.

The small group leader and staff presented three recommended algorithms for DBD older pediatric donors with lower KDPI, DBD younger pediatric donors with lower KDPI and liver and intestine available, and DBD younger pediatric donors with higher KDPI and liver and intestine available. The pediatric algorithms included the following:

- Increased priority for Heart Classifications 7 and 8 (Pediatric 1B within 500NM) (all 3 algorithms)
- Increased priority for Kidney Classification 6 (pediatric) (lower KDPI pediatric donors)
- Added several Liver Classifications
- Increased priority for Intestine Classifications 1-4 (all three algorithms)

The aim of the recommended algorithms was to increase access to transplant for pediatric candidates, including pediatric MVT candidates, in the context of pediatric donors.

Summary of discussion:

Concerns were raised about the prioritization of pediatric kidney candidates vs pancreas and kidney-pancreas candidates, particularly in relation to the potential for non-utilization of pancreata. For younger donors, members tended to support prioritization of pediatric candidates over pancreas and kidney-pancreas candidates. For older pediatric donors, members tended to support Kidney and Kidney-Pancreas Classifications 1-3 above pediatric kidney candidates. Members agreed to ask specific public comments on the prioritization of pediatric kidney candidates vs pancreas and kidney-pancreas candidates. The remainder of the discussion was reserved for agenda item 7. Finalize MOT allocation algorithms.

5. Lung-MOT work group report out

OPTN Contractor staff presented the Lung-MOT Workgroup report.

Presentation summary:

The workgroup requested and reviewed data on:

- Lung multi-organ candidate match run appearances under continuous distribution
- Risk of waitlist mortality and expected post-transplant survival by lung CAS
- Waiting list outcomes and median time to transplant for lung multi-organ candidates
- Waiting list and post-transplant survival for classifications included in multi-organ algorithm
- Median appearances on the match run for multi-organ donors

The workgroup has identified preliminary CAS thresholds identified for further analysis:

- Lower CAS threshold (less medically urgent/less priority):
 - All donors: 31
 - Non-O donor (A/AB/B): 31
 - O donor: 35
- Higher CAS threshold (higher medically urgency/priority):
 - Non-O donor (A/AB/B): 34
 - O donor: 39

The workgroup has also requested additional data for analysis:

- Number & proportion of candidates (all and MOT) that fall above the CAS thresholds across MOT donor match runs
- Distribution of medical urgency for candidates that fall above and below the CAS thresholds across MOT donor match runs

Summary of discussion:

The Committee did not make any decisions.

The Committee noted the recommendations and further data requests. Members expressed support for stratification of the lung CAS thresholds by blood type.

Next Steps: The workgroup will review further data and present any refinements to the recommended CAS thresholds to the full Committee.

6. Kidney small group report out

The small group leader presented on the recommended algorithm for DBD adult donors with higher KDPI.

Presentation summary:

The proposed algorithm is similar to the initial draft algorithm, except there is no classification for pediatric candidates within 250NM in the relevant policy table. The small group recommends the following for the algorithm for DBD adult donors with higher KDPI:

- Include additional groups of highly sensitized kidney candidates
- Include the highest priority pediatric candidates from the relevant policy table
- Increase priority for Classification 6 (medically urgent) kidney candidates (above Heart Classification 5)

Discussion was reserved for agenda item 7. Finalize MOT allocation algorithms.

7. Finalize MOT allocation algorithms

The Committee considered potential revisions to the initial draft algorithm and 5 additional donor algorithms recommended by the small groups.

Presentation summary:

OPTN contractor staff presented the relevant parts of NOTA and the Final Rule. Staff recapped the Committee’s values prioritization exercise (VPE) results. The Committee reviewed the initial draft algorithm with reference to:

- Median appearances
- Median WL survival
- Median PT survival
- Mean Time w/o offer
- % w/o offer

The Committee confirmed its rationale for inclusion of Classifications and the order of Classifications. The table below summarizes the Committee’s rationales:

Organ classification	Rationale for placement
Liver Class 1: Status 1A (adult and pediatric); 500NM	Medical urgency. No life-sustaining technology.
Heart Class 1: Adult Status 1 or Pediatric Status 1A; 500NM Heart Class 2: Adult Status 1 or Ped Status 1A; 500NM	Medical urgency.
Liver Class 2: Status 1B; 500NM Liver Class 3: Status 1A; HI or PR Liver Class 4: Status 1B; HI or PR	Medical urgency. Pediatric access to transplant.
Heart Class 3: Adult Status 2; 500NM Heart Class 4: Adult Status 2; 500NM	Medical urgency. Access to transplant.
Lung: Composite Allocation Score (CAS) to be determined	Ongoing analysis of lung CAS threshold.

Organ classification	Rationale for placement
Kidney Class 1: 0-ABDR mismatch; CPRA equal to 100%; 250NM Kidney Class 2: CPRA equal to 100%; 250NM Kidney Class 3: 0-ABDR mismatch; CPRA equal to 100%; nation Kidney Class 4: CPRA equal to 100%; nation	Access to transplant. Small population.
Kidney Class 5: Prior living donor; 250NM	Honor gift of life.
Liver Class 5: MELD/PELD of at least 37; 150NM Liver Class 6: MELD/PELD of at least 37; 150 NM Liver Class 7: MELD/PELD of at least 37; 250NM Liver Class 7: MELD/PELD of at least 37; 250NM Liver Class 9: MELD/PELD of at least 37; 500NM Liver Class 9: MELD/PELD of at least 37; 500NM Liver Class 11: MELD/PELD of at least 37; HI or PR Liver Class 12: MELD/PELD of at least 37; HI or PR	Medical urgency.
Intestine Class 1: Status 1; 500NM Intestine Class 2: Status 1; 500NM Intestine Class 3: Status 1; nation Intestine Class 4: Status 1; nation	Access to transplant. No life-sustaining technology.
Lung: Composite Allocation Score TBD	Ongoing analysis of lung CAS threshold.
Pancreas or K/P Class 1: 0-ABDR mismatch; CPRA ≥ 80%; 250NM Pancreas or K/P Class 2: CPRA ≥ 80%; 250NM	Access to transplant. Utilization of pancreata.
Heart Class 5: Adult Status 3 or Pediatric Status 1B; 250NM Heart Class 6: Adult Status 3 or Pediatric Status 1B; 250NM	Medical urgency and access to transplant for pediatric candidates.
Pancreas or K/P Class 3: 0-ABDR mismatch; CPRA ≥ 80%; nation Pancreas or K/P Classification 4: 250NM	Access to transplant. Utilization of pancreata.
Kidney Class 6: Registered prior to 18 years old; 250NM	Access to transplant for pediatric candidates.
Kidney Class 7: Medically Urgent; 250NM	Medical urgency.
Kidney Class 8: 0-ABDR mismatch; CPRA equal to 99%; 250NM Kidney Class 9: CPRA equal to 99%; 250NM Kidney Class 10: 0-ABDR mismatch; CPRA equal to 98%; 250NM Kidney Class 11: CPRA equal to 98%; 250NM	Access to transplant.
Liver Class 13: MELD/PELD of at least 33; 150NM Liver Class 14: MELD/PELD of at least 33; 150NM Liver Class 15: MELD/PELD of at least 33; 250NM Liver Class 16: MELD/PELD of at least 33; 250NM Liver Class 17: MELD/PELD of at least 33; 500NM Liver Class 18: MELD/PELD of at least 33; 500NM Liver Class 19: MELD/PELD of at least 30; O donor; O or B candidate; 150NM Liver Class 20: MELD/PELD of at least 29; O donor; O candidate; 150NM Liver Class 21: MELD/PELD of at least 29; non-O donor; any cand.; 150NM Liver Class 22: MELD/PELD of at least 30; O donor; O or B candidate; 250NM Liver Class 23: MELD/PELD of at least 29; O donor; O candidate; 250NM Liver Class 24: MELD/PELD of at least 29; non-O donor; any cand.; 250NM Liver Class 25: MELD/PELD of at least 30; O donor; O or B candidate; 500NM Liver Class 26: MELD/PELD of at least 29; O donor; O candidate; 500NM Liver Class 27: MELD/PELD of at least 29; O donor; O candidate; 500NM	Medical urgency.

Next, the Committee walked through the other donor algorithms to consider any revisions and opportunities for calibration across the algorithms. The Committee agreed to add some groups of highly sensitized kidney candidates and some lower MELD/PELD liver classifications to the algorithms.

Summary of discussion:

The Committee made revisions to the algorithms for inclusion in the public comment update.

Members discussed challenging questions of prioritization and requested specific questions on these issues for inclusion in the public comment update:

- In all algorithms, are Kidney Classifications 1-4 (highly sensitized) candidates appropriately prioritized relative to the other organ classifications?
- In all algorithms, are Kidney Classification 5 (prior living donor) candidates appropriately prioritized relative to the other organ classifications?
- In the table for DBD adult donors with lower KDPI, are Pancreas/Kidney-Pancreas Classifications 1-4 (highly sensitized candidates and all candidates within 250NM), Heart Classifications 5-6 (Adult Status 3 and Pediatric Status 1B within 250NM), and Kidney Classifications 6 (registered prior to 18 years within 250NM) and 7 (medically urgent within 250NM) appropriately prioritized?
- In the tables for older pediatric donors with lower KDPI, should Kidney Classification 6 (registered prior to 18 years) be placed above Pancreas/Kidney-Pancreas Classification 1 (highly sensitized within 250NM), between Pancreas/Kidney-Pancreas Classification 3 (highly sensitized, nation) and 4 (all candidates within 250NM), or below Pancreas/Kidney-Pancreas Classification 4 (all candidates within 250NM)?
- In the tables for younger pediatric donors with lower KDPI, should Kidney Classification 6 (registered prior to 18 years) be placed above Pancreas/Kidney-Pancreas Classification 1 (highly sensitized within 250NM), between Pancreas/Kidney-Pancreas Classification 3 (highly sensitized, nation) and 4 (all candidates within 250NM), or below Pancreas/Kidney-Pancreas Classification 4 (all candidates within 250NM)?
- In the table for younger pediatric donors with higher KDPI, should Kidney Classifications 7-14 (CPRA of 98% or greater; or 0-ABDR mismatch within 250NM; or 0-ABDR mismatch pediatric candidates, national) be included in the table?

Next steps: The final algorithms and public comment questions will be included in the public comment update.

8. Laterality small group report out

The small group leader presented options for streamlining laterality policy in the upcoming policy proposal.

Presentation summary:

The group reviewed OPTN *Policy 8.6.A: Choice of Right versus Left Donor Kidney*. It recommends that the candidate with highest priority within the relevant algorithm chooses which kidney they receive. It recommends striking the second paragraph of *Policy 8.6.A* and adding language to the first paragraph to account for the new algorithms.

Summary of discussion:

The Committee agreed that revisions to OPTN *Policy 8.6.A: Choice of Right versus Left Donor Kidney* should be included in the upcoming policy proposal.

A member questioned whether pediatric candidates should be prioritized for choice of right versus left donor kidney. Other members questioned how this approach could be operationalized. Members noted that choice is not necessary for pediatric patients, as many pediatric programs are successfully transplanting left or right donor kidneys.

Next steps: The agreed changes will be included in the upcoming policy proposal.

9. Public comment and feedback questions

OPTN Contractor staff presented the potential opportunities for feedback.

Presentation summary:

Staff discussed potential opportunities for feedback:

- Public comment update
- Regional meetings
- Cross-Committee presentations/Ex-Comm/BOD
- Public comment webinar
- Conferences/professional meetings
- Consensus conference
- Further OPO user research

Staff requested feedback on effective communication strategies. They requested feedback on what information should be included in the update.

Summary of discussion:

The Committee did not make any decisions.

Committee members suggested using story telling techniques to articulate the problems (order of priority and operational challenges). They emphasized the need for donor and patient centered language and graphics to help communicate complex information in a user friendly manner. They called for clear examples of how allocation would work under proposed policy. They agreed it would be helpful to note diversity of Committee members, their systems approach, and difficult compromises. They suggested limiting data in the results and included it in supplemental materials. They called for FAQs for regional meetings and cross-Committee presentations.

Upcoming Meetings

- November 13, 2024

Attendance

- **Committee Members**
 - Lisa Stocks, Chair
 - Zoe Stewart Lewis, Chair
 - Vincent Casingal
 - Chris Curran
 - Rocky Daly
 - Jonathan Fridell
 - Rachel Engen
 - Shelley Hall
 - Jim Kim
 - Precious McCowan
 - Oyedolamu Olaitan
 - Nagai Shunji
 - Deanna Santana
 - Chris Sonnenday
 - Nicole Turgeon
 - Anji Wall
- **HRSA Representatives**
 - Marilyn Levi
 - Jim Bowman
- **SRTR Staff**
 - Katie Audette
 - Jon Miller
- **UNOS Staff**
 - Viktoria Filatova
 - Sara Langham
 - Katrina Gauntt
 - Houlder Hudgins
 - Sarah Roache
 - Kaitlin Swanner
 - Susan Tlusty
 - Ross Walton