**OPTN Ad Hoc Multi-Organ Transplantation Committee**
**Meeting Summary**
**April 3, 2024**
**Conference Call**

**Lisa Stocks, RN, MSN, FNP, Chair**

## Introduction

The Ad Hoc Multi-Organ Transplantation (MOT) Committee, the Committee, met via WebEx teleconference on 04/03/2024 to discuss the following agenda items:

1. Modify Effect of Acceptance Policy Proposal: Public Comment Feedback
2. Modify Effect of Acceptance Policy Proposal: Proposed Changes (Vote)
3. Concepts for Modifying MOT Policies: Public Comment Feedback
4. Draft MOT Allocation Scheme
5. Data to Inform Allocation Scheme
6. Values Prioritization Exercise to Inform Allocation Scheme
7. Identify Priority Shares in Kidney Multi-Organ Policies
8. Lung CAS Threshold

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

## 1. Modify Effect of Acceptance Policy Proposal: Public Comment Feedback

The Chair and OPTN contractor staff reviewed public comment feedback received on the Committee's *Modify Effect of Acceptance Policy* proposal.[1]

Presentation summary:

- The proposal received 309 comments from all member types across 40 states
- Public comment was supportive, with sentiment scores of 4.1 by member type and 4.1 by region
- Commenters supported the proposal because it would increase efficiency of organ placements and help avoid last-minute redirections from single to MOT candidates
- Commenters called for clarification of the meaning of acceptance
- There was slightly more support for not specifying a timeframe in policy language

Summary of discussion:

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

## 2. Modify Effect of Acceptance Policy Proposal: Proposed Changes (Vote)

The Chair and OPTN contractor staff reviewed proposed post-public comment revisions to the *Modify Effect of Acceptance Policy*.

Presentation summary:

[1] "Modify Effect of Acceptance Policy," OPTN, Public Comment Proposal, available https://optn.transplant.hrsa.gov/media/vnvlezd1/mot_modify-policy-effect-of-acceptance_pcjan24.pdf.

- The Committee reviewed proposed changes to policy language to address public comment feedback:
    - To help clarify the meaning of acceptance, inserting reference to acceptance for a "primary potential transplant recipient," which is defined in policy as "[t]he first candidate according to match run sequence for whom an organ has been accepted."
    - To ensure that OPOs can continue to make backup offers after acceptance, removing "including those according to Policy 5.10: Allocation of Multi-Organ Combinations …"
    - To allow OPOs flexibility to proceed with multi-organ offers after acceptance, inserting "not required to be offered according to Policy 5.10: Allocation of Multi-Organ Combinations …"
- OPTN contractor staff presented opportunities for educational resources to support OPOs and other stakeholders implementing the policy change and related policies, including organ offer acceptance, immediate reporting of acceptance, potential transplant recipient, primary potential transplant recipient, and backup offers

Summary of discussion:

A member expressed support for the policy, based on his experience in kidney-pancreas (KP) and pancreas transplantations. A member called for input from the perspectives of Organ Procurement Organizations (OPOs), to ensure that it reflects the realities of their experiences and can be effectively implemented. Another member affirmed that the language of the changes is unambiguous and effectively captures the intended modifications. The member confirmed that this clarity fulfills a longstanding need within many OPOs and that the revised language would addresses concerns and facilitate smoother implementation processes.

A member expressed concern that there may be ongoing confusion about provisional and final acceptances. The Chair acknowledged the potential for confusion and emphasized the Committee's responsibility to advocate for educational efforts on this matter. Adding to the conversation, a representative from an OPO confirmed that most individuals within the OPO community comprehend the difference between "provisional yes" and organ acceptance. However, the member highlighted that there can be ambiguity, particularly concerning kidneys, as decisions may be contingent on the availability of anatomical and biopsy data.

A member questioned the proposed revision that will allow OPOs flexibility to proceed with multi-organ offers after acceptance. Another member clarified that the revised language introduces a degree of flexibility for OPOs, providing them with greater discretion in allocation decisions.

The Chair called for a vote on the policy proposal, which was seconded by a member.

**Vote: Does the Committee agree to recommend the amended policy language to the Board of Directors?**

**Yes (13), No (0), Abstain (0)**

The Committee also agreed that the OPTN contractor should develop educational resources to promote awareness of and compliance with *Policy 5.6.D: Effect of Acceptance* and related policies and definitions.

Next steps:

- The *Modify Effect of Acceptance Policy* proposal will be considered by the Board of Directors at its June meeting
- If approved, the OPTN contractor will roll out educational resources to support implementation

### 3. Concepts for Modifying Multi-Organ Policies: Public Comment Feedback

The Chair and OPTN contractor staff reviewed public comment feedback received on the Committee's *Concepts for Modifying Multi-Organ Policies* request for feedback. [2]

Presentation summary:

- The request for feedback received 112 comments from all member types across 26 states
- There was broad support for policy directing MOT allocation order
    - Commenters suggested metrics to determine priority including medical urgency, post-transplant outcomes, and accrued waiting time
- On the topic of prioritizing MOT and kidney alone candidates, comments indicated:
    - Support for prioritizing kidney-alone pediatric, highly-sensitized, medically urgent, and prior living donors
    - No clear consensus on the order of priority among MOT candidates, priority kidney alone candidates, and kidney-pancreas candidates
    - Support categorizing kidney-pancreas candidates as part of the kidney alone pool, though some commenters and regional meetings could not reach consensus
    - Support for 1 kidney to MOT and 1 kidney to the kidney alone list

Summary of discussion:

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

### 4. Draft MOT Allocation Scheme

The Committee discussed its ongoing development of a ranked list in policy for OPOs to follow when there are multiple candidates that qualify for required MOT shares on different match runs.

Presentation summary:

- The Committee's approach is to develop an initial draft list and identify outstanding questions; to review data and ensure alignment; and where data is insufficient, to use a values prioritization exercise (VPE) to help determine clinical consensus
- The scope of the project is to 1) prioritize between MOT combinations appearing on different match runs; and 2) prioritize between MOT candidates and single-organ candidates on different match runs
- Eight Committee members completed a survey, which asked them to review the initial ranked list and suggest any changes they would make to the order
- The survey results suggested the following changes for the Committee's consideration:
    - Move Liver Classification 1 above Lung CAS threshold for required multi-organ shares
    - Move Liver Classifications 5 and 6 above some Intestine Classifications
    - Increased priority for Kidney Classifications 1, 2, and 3
    - Increased priority for Heart Classifications 5 and 6

Summary of discussion:

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

[2] "Concepts for Modifying Multi-Organ Policies," OPTN, Request for Feedback, available https://optn.transplant.hrsa.gov/media/hu3ovwas/mot_request-for-feedback_january-2024.pdf.

During discussions, the group explored the potential implications of moving kidney classification 1-4 to the top of the list. One member noted that the outcome would vary depending on whether the Committee decided that one kidney should be allocated to an MOT recipient and the other to a kidney-alone candidate. Another member expressed his belief that medically urgent kidneys should be prioritized immediately after higher classes of liver, heart, and lung patients. He highlighted his surprise at their lower prioritization despite their urgency and relatively few cases. In response, the Chair noted that it is out of scope for the MOT Committee to determine how candidates are ranked on individual organ match runs. She stated that the MOT Committee's role is to determine allocation based on existing policy rather than proposing specific changes in relation to individual organ match runs.

Next steps:

The Committee will explore various data and analysis options and consider a VPE to inform the remaining decision points within the allocation scheme.

**5. Data to Inform Draft MOT Allocation Scheme**

The Committee considered potential data topics and questions that could inform decision making processes as it relates to the MOT allocation scheme.

Presentation summary:

- Proposed research questions:
    - How do multi-organ and single-organ candidates listed on different match runs compare in terms of waitlist mortality?
    - What does donor availability look like for MOT candidates?
- Proposed data analysis:
    - Analyze pre-transplant risks for all patients waiting for any organ or combination

Summary of discussion:

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

The Chair invited Committee feedback on the proposed research questions and data analysis. One member suggested that waitlist mortality could serve as a valuable metric for informing discussions on prioritizing patients, as it aligns with the Final Rule's principle of prioritizing patients based on medical urgency. Additionally, the member proposed examining organ non-use to identify organs at the highest risk of waste. Another member echoed the importance of waitlist mortality, emphasizing its defensibility in prioritization conversations and suggested stratifying data by different classifications for more comprehensive insights. When asked about the role of waitlist mortality data in allocation changes, the Chair indicated that it would primarily serve as a reference point to guide discussions on prioritization decisions.

When discussing mortality risk factors, Committee members highlighted considerations such as different classifications, scoring systems, and time on the waitlist. One member pointed out a limitation regarding factors not currently included in the classification scheme, which cannot be used for prioritization stratification. Another member advocated for the inclusion of the time to next offer tool as a mortality aspect, suggesting that a longer time to the next offer could imply a higher mortality risk. Regarding outcomes, a member inquired about the possibility of separate outcomes when only one organ is transplanted. The OPTN contractor staff responded, suggesting that the Committee should consider including this criterion and indicating that it could be incorporated into the model. However, they acknowledged the need for further consideration when devising an analysis plan.

Regarding the cohort for data analysis and the timeframe under consideration, a member expressed concerns about the potential impact of policy changes overtime for MOT combinations and individual organs. The member noted that these changes might result in the Committee never obtaining a homogeneous cohort of MOT recipients who have experienced consistent allocation policies. Despite the common principle of medical urgency in all allocation systems, she emphasized that the data and waiting periods would vary, leading to potential discrepancies in the analyses.

Concerning the proposed research question about donor availability for MOT candidates, the Chair commented that it would provide valuable insights, differing somewhat from past data analyses focusing on KDPI donors allocated to MOT candidates. She noted that this approach would involve examining the overall pool of donors. Another member emphasized the need to differentiate between types of MOT candidates who may require different types of kidneys when considering donor availability. However, another member cautioned against solely examining donors in isolation, as MOT candidates vary in their specific needs and characteristics. Additionally, a member suggested considering kidneys with a KDPI higher than 0-34%, noting that not all MOT candidates require a low KDPI kidney.

Next steps:

OPTN contractor staff and Scientific Registry of Transplant Recipients (SRTR) staff will consider the Committee's feedback and refine the proposed research questions and data analyses.

**6. Values Prioritization Exercise to Inform Draft MOT Allocation Scheme**

The Committee considered developing a VPE to inform the draft MOT allocation scheme.

Presentation Summary:

- A VPE is an exercise to elicit the community's values in a structured format
- For the purposes of the MOT Committee and the questions they are attempting to answer, the VPE would ask participants to compare candidate profiles to elicit which attributes (e.e medical urgency, waiting time, age group) are most important in determining priority

Summary of discussion:

**Decision: The Committee decided to proceed with the development of a values prioritization exercise**

A member emphasized the utility of a VPE but expressed concern about the limited feedback due to the small size of the MOT Committee. The member proposed extending the VPE to leadership of organ-specific committees to gather insights from individuals familiar with the intricacies of MOT allocation. However, another member voiced apprehensions about the effectiveness of the VPE, highlighting the absence of real-time information on alternatives available to recipients if they decline an organ offer. The member commented that the VPE may oversimplify complexities of MOT allocation. In response, the Chair suggested soliciting input from the Committee to determine the attributes and comparisons that will be most relevant to the Committee's goals.

A member highlighted the challenge of participants possessing in-depth knowledge of their respective organs but lacking understanding of other organ classifications, potentially leading to divergent responses. The member stressed the need for additional education and data analysis to ensure informed participation. Another member agreed, noting that perspectives may vary based on roles within the transplant process, suggesting preliminary education on each organ combination before the VPE. Additionally, a member recommended incorporating attributes like high CPRA and living donor status into the exercise.

Next steps:

OPTN contractor staff will consider the Committee's feedback and further develop the VPE.

**7. Identify Priority Shares in Kidney MOT Policies**

The Committee discussed how MOT and kidney-alone candidates should be prioritized in allocation policy.

Presentation summary:

The Committee was asked to consider several policy questions:

- Should KP candidates be classified as MOT or as part of kidney-alone pool?
- How should MOT candidates be prioritized when there are 2 kidneys (0-34%)?
- How should MOT candidates be prioritized when there are 2 kidneys (35-85%)?
- How should MOT candidates be prioritized when there is 1 kidney (0-34%)?
- How should MOT candidates be prioritized when there is 1 kidney (35-85%)?

It was also asked to consider where two kidneys are available, whether one kidney should be allocated to the MOT allocation scheme and one kidney to the kidney-alone list or whether both kidneys should be allocated to the MOT allocation scheme with kidney classifications incorporated into the scheme.

Summary of discussion:

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

The Committee engaged in a discussion regarding the policy question of how to allocate kidneys when two are available. One member opposed prioritizing KP patients over MOT candidates, potentially decreasing the number of MOTs without much impact on the kidney-alone list. The member commented that this complex policy might not effectively address the intended goals.

A member supported the one to MOT and one to kidney-alone approach, seeing it as similar to current allocation practice. Another member suggested exploring different ways to prioritize KP and other kidney classifications. Another member cited allocation practices favoring KPs and questioning the threshold at which prioritizing other kidney classifications justifies losing a pancreas for transplantation. The Chair noted the importance of maximizing organ utilization.

One member emphasized the importance of providing prioritization for pediatric patients if KPs are grouped with the kidney-alone pool. She expressed concerns that KP candidates may divert kidneys away from pediatric candidates and advocated for prioritizing kidney classifications 1-4 in this scenario. Another member noted that many individuals support classifying KPs as part of the kidney-alone list, as many KP candidates initially start off as kidney-alone candidates. He suggested focusing on determining the appropriate placement of KP candidates within the kidney-alone list. The Committee supported grouping KP with the kidney-alone list when a 0-34% KDPI donor kidney is being considered.

Next steps:

These decisions will be further informed by the data request and analysis and by the VPE.

**8. Lung CAS Threshold**

The Committee reviewed regional meeting and taskforce feedback and considered options for adjusting the lung CAS threshold for MOT shares involving lungs.

Presentation Summary:

- Regional meeting feedback and feedback from taskforce sessions indicates that the current CAS threshold may be causing allocation delays
- Options for adjusting CAS threshold to address delays include:
    - Explore raising CAS threshold
    - Explore defining cut-off point based on other factors percentage of the match run

Summary of discussion:

**Decision: The Committee decided to review data from the Lung 1-year CD monitoring report to inform its work on lung CAS threshold for MOT shares involving lungs.**

A representative from the lung committee suggested that the forthcoming Lung one-year monitoring report may further inform the Committee's work on this issue. The member proposed the formation of a task force or subcommittee within the lung committee to assist with challenges related to liver-lung and heart-lung combinations. The Chair agreed with these suggestions. In response to a query about potentially raising the lung CAS threshold, the member indicated that she believed only one cutoff would be necessary within the MOT allocation scheme. She explained that the lung committee recognizes the priority of Status 1 livers and expressed confidence in integrating any changes to the CAS threshold into the draft allocation scheme without the need for additional CAS thresholds.

Next steps:

The Committee will reconsider this topic once it reviews the one-year monitoring report.

**Upcoming Meeting**

- April 17, 2024

**Attendance**

- **Committee Members**
  - Lisa Stocks, Chair
  - Sandra Amaral
  - Marie Budev
  - Vincent Casingal
  - Chris Curran
  - Rachel Engen
  - Jonathan Fridell
  - Shelley Hall
  - Kenny Laferriere
  - Heather Miller Webb
  - Oyedolamu Olaitan
  - Jennifer Prinz
  - Nicole Turgeon
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Katie Audette
  - Jon Miller
- **UNOS Staff**
  - Jessica Higgins
  - Houlder Hudgins
  - Sara Langham
  - Taylor Michalski
  - Jamie Panko
  - Jenna Reformina
  - Sarah Roache
  - Laura Schmitt
  - Kaitlin Swanner
  - Susan Tlusty