

**OPTN Ethics Committee  
Meeting Summary  
February 15<sup>th</sup>, 2024  
Conference Call**

**Andrew Flescher, PhD, Chair  
Sanjay Kulkarni, MD, Vice Chair**

## Introduction

The Ethics Committee (“Committee”) met via WebEx teleconference on 02/15/2024 to discuss the following agenda items:

1. Presentation on Allocation Out of Sequence
2. OPTN Ad-Hoc Multi-Organ Transplantation Committee Request for Feedback: Concepts for Modifying Multi-Organ Policies

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

### 1. Presentation on Allocation Out of Sequence

The Committee heard a presentation regarding allocation out of sequence in preparation for their next project idea.

#### Presentation Summary:

Expedited Placement is Consistent with NOTA and the Final Rule. The Final Rule requires that allocation policies:

- seek to achieve the best use of donated organs
- ***designed to avoid wasting organs***, to avoid futile transplants, to promote patient access to transplantation, and ***to promote the efficient management of organ placement***

Inefficiencies in this process include:

- Transplant programs overwhelmed with number of organ offers
- Inadequate review of donor organ offers or proactive review with clinical decision makers
- Request for additional testing despite no indication
- Determination of candidate availability/suitability/compatibility
- Results in Late Declines and Risk of non-transplant
  - Pre-recovery vs. post recovery
  - Pre-recovery extra-renal organ logistical considerations necessary Travel
    - Candidate travel, admission and pre-transplant preparations
    - Machine Perfusion
    - Recovery Surgeons
- Unintended Consequences of well-intentioned policies
  - Multi-Organ Allocation
    - Example: Lung/Liver for CAS > 25
  - Multiple Acceptances for Individual Candidates
  - Broader Sharing
    - Acceptance reversal due to acceptance of another organ

- Histocompatibility Variability
- Geographic Differences
  - Concentration of Programs in a Geographic area
    - Ability to identify right candidate without bypasses
- Clinical Decision Making (right candidate for the right organ)
  - Decline of a transplantable organ based on intra-operative assessment

Expedited Pathways can include:

- Expedited Liver Wizard
- While Following the list...
  - Programs declines for top candidates, indicates interest at lower sequence
  - Decision to allow acceptance or continue following match run?
    - Determined by combination of factors and leadership decision-maker
  - Multiple programs expressing interest, determine by rank
- Local Prioritization
  - Decreased travel/Ischemic time/Knowledge or Practices
  - Small number centers in circle = fewer bypasses
- “Aggressive” Centers
  - Subjective: Word of mouth/Program Declaration
  - Objective: Transplant Volume/Acceptance Rates/Practices
  - Determination of Order (proximity? Top candidate on match?)

The presenters also explained ways to increase utilization and ways to decrease late declines.

Summary of discussion:

A member explained that the OPTN is also required to follow other criteria beyond what was outlined in the presentation when designing allocation policies, noting that it is a balancing act of the criteria and regulations.

A member asked the presenters for their thoughts on how expedited placement pathways have impacted equity in access to transplantation. One presenter explained that this is a big concern, and that the OPOs in general try to avoid getting to the point where expedited placement has to be used in sort of a “band-aid” approach. They continued by saying that the way to promote equity is by building an efficient system to get to the right patients and by building an objective pathway to treat all candidates fairly. The Vice Chair agreed that equity is a major concern, noting that the OPO open offer is just the beginning of equity concerns. The Vice Chair went on to explain that during expedited placement in an open offer, transplant centers are making decisions out of the order of the match run to place the organ.

A member asked if the presenters had a sense of if out of sequence allocations are rising, noting that in their experience, the new OPO performance metrics have led to an increase. A presenter agreed that the number of out of sequence offers are rising, but that it can be hard to pinpoint the reason for this.

**2. OPTN Ad-Hoc Multi-Organ Transplantation Committee Request for Feedback: Concepts for Modifying Multi-Organ Policies**

The Committee heard a public comment presentation on the OPTN Ad-Hoc Multi-Organ Transplantation Committee’s Request for Feedback on their paper, Concepts for Modifying Multi-Organ Policies.

### Presentation Summary:

From January – March 2023, the Ad Hoc Multi-Organ Transplantation Committee (Committee) requested feedback on the concept paper Identify Priority Shares in Kidney-Multi-Organ Allocation.<sup>1</sup> The concept paper was the first step in a project that aims to improve equity in access to transplant between kidney-alone and kidney multi-organ candidates, and to improve efficiency in allocating multiple organ types from one donor. The Committee has been reviewing public comment feedback, evaluating data, and requests additional input on these topics. The purpose of this request for feedback is to gather additional community input on prioritization of single kidney candidates compared to multi-organ candidates, as well as policy guidance for general multi-organ (MOT) allocation.

The Committee requests feedback on all aspects of this paper, including the following questions:

#### *MOT vs. Single Kidney Offers*

- Do patients and donor family members support efforts to improve access to transplant for kidney candidates, even if it means that candidates registered for multiple organs may need to wait longer for a suitable donor?
- Should kidney-pancreas candidates be considered multi-organ candidates?
- When both kidneys are available from a donor with a KDPI between 0-34 percent:
  - Should one kidney be allocated to MOT (including KP), second kidney to kidney alone?
  - Should one kidney be allocated to MOT, second kidney to KP or kidney alone?
  - What are the potential impacts to KP and pediatric candidates?
- How should MOT candidates be prioritized when there is only one kidney available?

#### *Policy Guidance for OPOs*

- Should policy direct the order in which OPOs allocate organs? If so, how should expected waitlist mortality or graft survival be incorporated into the prioritization of candidates across different match runs?
- What additional policy or system considerations would OPOs need to follow a match run order directed by policy?
- Do patients and donor family members support efforts to promote more consistency in how organ allocation is managed by OPOs across the country?

### Summary of discussion:

The Vice Chair commented that there is a lot of clinical decision making involved with these questions. He mentioned that it is not surprising that pancreas candidates and clinicians would be concerned: because of the need to be highly selective with pancreas, if pancreas offers are not prioritized, then this may lead to extended waiting time for kidney-pancreas candidates.

A member explained that looking into how the question of multi-organ versus kidney-pancreas has impacted waiting time for pediatric patients and others prioritized for 0-20 percent KDPI kidneys would be important to consider. This member also explained that non-use of the pancreas is a concern. The presenter answered that the urgent need patients were a small group, however, that they did find that pediatric patients were at a disadvantage. The presenter explained that OPOs are supposed to allocate all organs, but that it is challenging to allocate a pancreas alone, so it often gets paired with a kidney for a kidney-pancreas offer.

A member commented that it is hard to weigh in on these questions without knowing the outcomes for the organ combinations. This member also explained that a concern is the timing of release for organs, noting that there are organs held for possible multi-organ transplant where no match is found. Then, the

organs are released for general allocation at a point where it is challenging to find matches for the individual organs, especially pancreas. The presenter answered that this is a good point, and something that the MOT Committee hopes to address with their policy proposal also out for public comment.

A member commented that it should not be up to individual OPOs to decide, but recommended a common algorithm across all OPOs.

#### **Upcoming Meeting**

- March 14, 2024 (in-person in Houston)

## Attendance

- **Committee Members**
  - Felicia Wells-Williams
  - Lois Shepherd
  - Andrew Flescher
  - Sanjay Kulkarni
  - Ehab Saad
  - Keren Ladin
  - Shelia Nichols-Bullock
  - Sena Wilson-Sheehan
  - Jen Dillon
  - Carrie Thiessen
  - Andrew Courtwright
  - Lisa Paolillo
  - Laura Jokimaki
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
  - Maryam Valapour
- **UNOS Staff**
  - Kieran McMahon
  - Cole Fox
  - Laura Schmitt
  - Joel Newman
  - Kristina Hogan
  - Sarah Roache
  - James Alcorn
- **Other Attendees**
  - Laura Butler
  - Chris Curran
  - Jillian Wojtowicz
  - Lisa Stocks