OPTN Ad Hoc Multi-Organ Transplantation Committee
Meeting Summary
June 12, 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 6/12/2024 to discuss the following agenda items:

1. Updates and Timeline for MOT Allocation Scheme Proposal
2. Organ Snapshots: Liver, Intestine, Kidney, and Pancreas
3. Values Prioritization Exercise: Design and Example Profiles
4. Recognition of Outgoing Members

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

1. Updates and Timeline

Staff provided updates and discussed the timeline for the development of a multi-organ allocation scheme that will help organ procurement organizations (OPOs) prioritize MOT and single-organ candidates on different match runs.

Summary of Presentation:

Staff informed members that the Modify the Effect of Acceptance policy change was approved by the OPTN Board of Directors on June 12, 2024, with a targeted implementation date of July 25, 2024.

Staff informed the members that the in-person meeting date of August 8, 2024, has been confirmed and travel information will be provided soon. The meeting will be held in Richmond, Virginia.

Staff provided a reminder of the timeline for developing an MOT allocation scheme proposal. The process will include a values prioritization exercise and review of both descriptive and modeling data during the August 2024 meeting. The plan is to develop policy language during the fall and distribute a policy proposal during the Winter 2025 public comment period.

Summary of Discussion:

The Committee did not make any decisions.

- There were no comments or questions from the committee members.

2. Organ Snapshots: Liver, Intestine, Kidney, and Pancreas

Representatives from the various organ types presented an overview of allocation policy for each organ type. The intent of this review was to increase committee members' understanding of candidates listed for organs outside their area of expertise. This will also help inform development of the values prioritization exercise.

Presentation summary:

Liver Allocation

The Liver and Intestinal Organ Transplantation Committee representative provided an overview of liver statuses for both adult and pediatric candidates, as shown below:

Adult

- Adult Status 1A: Reserved for candidates 18 years or older
  - Candidate has a life expectancy without liver transplant of less than 7 days
  - Has at least one of the following:
    - Fulminant liver failure
    - Anhepatic
    - Primary non-function of a transplanted whole liver within 7 days of transplant
    - Non-function within 7-days of transplant of a transplanted liver segment from a deceased or living donor
    - Hepatic artery thrombosis within 7-days of transplant
    - Acute decompensated Wilson's disease

- Model for End Stage Liver Disease (MELD) score - (6-40)
  - A score that reflects the probability of death within a 3-month period; utilized for candidates 12 years and older; on a scale of 6-40
    - Calculated MELD score: based on current lab values
    - Exception MELD score: an adjustment to the score based on an approved or assigned standard or non-standard exception request

Pediatric

- Pediatric Status 1A: Reserved for candidates less than 18 years of age at time of registration
  - Has at least one of the following:
    - Fulminant liver failure
    - Diagnosis of primary non-function of a transplanted liver within 7 days of transplant
    - Diagnosis of hepatic artery thrombosis in a transplanted liver within 14 days of transplant
    - Acute decompensated Wilson's disease
- Pediatric Status 1B: Reserved for candidates less than 18 years of age at time of registration
  - Has at least one of the following:
    - Fulminant liver failure
    - Diagnosis of primary non-function of a transplanted liver within 7 days of transplant
    - Diagnosis of hepatic artery thrombosis in a transplanted liver within 14 days of transplant
    - Acute decompensated Wilson's disease
- MELD or Pediatric End Stage Liver Disease (PELD) - (6-99)
  - A score that reflects the probability of death within a 3-month period; utilized for candidates 12 years and older; on a scale of 6-40
    - Calculated MELD score: based on current lab values
    - Exception MELD score: an adjustment to the score based on an approved or assigned standard or non-standard exception request

Standard Exceptions

- Exceptions: an adjustment to the score based on an approved or assigned standard or non-standard exception request
- Exception scores are assigned relative to mean MELD at transplant (MMaT) or mean PELD at transplant (MPaT)
- Nine standard exceptions in policy, if candidate meets criteria, they are automatically approved for a score adjustment:
  - Hilar cholangiocarcinoma
  - Cystic fibrosis
  - Familial amyloid polyneuropathy
  - Hepatic artery thrombosis
  - Hepatopulmonary syndrome
  - Metabolic disease
  - Portopulmonary hypertension
  - Primary hyperoxaluria
  - Hepatocellular carcinoma
- All other exceptions are considered non-standard and require review and approval by the National Liver Review Board (NLRB)

Intestine Allocation

Intestine allocation policy is based on the following medical urgency statuses:

Status 1

Candidate must have any of the following conditions:

- Liver function test abnormalities
- No vascular access through the subclavian, jugular, or femoral veins for intravenous feeding
- Medical indications that warrant intestinal organ transplantation on an urgent basis

Status 2

Any active candidate that does not meet the criteria for Status 1 must be registered as Status 2.

Summary of discussion:

The Committee did not make any decisions.

A member asked why the MELD/PELD score was capped at 40. The Liver Committee representative responded that once a candidate reaches a MELD or PELD score of 40 they are most likely to be transplanted quickly so it is not helpful to have higher scores.

A member asked if there was an estimated time to transplant for liver candidates. Staff noted that the information was not available but will be provided as part of the upcoming data request report. The Liver Committee representative responded that candidates with a MELD/PELD score of 40 will typically get transplanted within a week, and candidates with a MELD/PELD score of 34-40 get transplanted within a couple of weeks.

A member asked about the scenario where a candidate is Status 1 for intestine but have a lower MELD score. The Liver Committee representative responded that for multi-visceral candidates the liver is usually the primary organ.

A member commented that it might be time to revisit the MELD/PELD score cap because waiting time is the tiebreaker. Another member responded that broader sharing has reduced wait times, and normothermic regional perfusion (NRP) has increased the use of donation after circulatory death (DCD) donors for livers.

Kidney Allocation

An MOT Committee member provided an overview of current kidney allocation policies.

Summary of Presentation:

Kidney allocation policy is driven by donor and candidate characteristics. Several types of candidate profiles are prioritized:

- High CPRA (highly sensitized), Prior Living Donor, Medically Urgent, Pediatric, Safety Net Kidney, Top 20% EPTS candidates, and 0-ABDR mismatch
- Candidates across categorizations are generally prioritized by distance (250 nautical mile circles)
- Candidates within classifications are generally prioritized by time waiting and with such a large population of kidney candidates, waiting time becomes a huge driver.

Donor/Organ expected longevity kidney donor profile index (KDPI) drives which groups are prioritized.

- For example, pediatric candidates would be unlikely to accept high KDPI/low longevity kidneys, and thus are not prioritized for the highest KDPI kidneys.
- Note that KDPI was validated for adult donor kidneys and there have been concerns that the KDPI is falsely elevated in pediatric kidney donors, resulting in many pediatric kidneys being misclassified and not offered to children.

Candidate Characteristics for Kidney:

- CPRA
- 0-ABDR mismatch
- Prior living donors
- Medically urgent
- Pediatric priority
- Safety net criteria

Donor Profile Types

- Sequence A – KDPI 0-20% (and en bloc)
- Sequence B – KDPI 20-34%
- Sequence C – KDPI 35-85%
- Sequence D – KDPI 86-100%

Pancreas Allocation

Summary of Presentation:

An MOT Committee member provided an overview of current pancreas allocation policies.

Registration

- Candidates must meet one of the following requirements:
    - Be diagnosed with diabetes
    - Have pancreatic exocrine insufficiency

    - Require the procurement or transplantation of a pancreas as part of a multiple organ transplant for technical reasons
- Combined Kidney-Pancreas Registration
    - Candidates must be diagnosed with diabetes or have pancreatic exocrine insufficiency with renal insufficiency

Policy 11.3.B: Kidney-Pancreas Waiting Time Criteria for Candidates at Least 18 Years Old

1. The candidate is registered for a kidney-pancreas
2. The candidate qualifies for kidney waiting time according to Policy 8.3.A: Waiting Time
    1. The candidate's registration date with a glomerular filtration rate (GFR) or measured or estimated creatinine clearance (CrCl) less than or equal to 20 mL/min
    2. The date after registration that a candidate's GFR or measured or estimated CrCl becomes less than or equal to 20 mL/min
    3. The date that the candidate began regularly administered dialysis as an End Stage Renal Disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting
3. The candidate is on insulin

Pancreas Allocation Order

If an OPO has both a kidney and a pancreas available for allocation, the OPO:
- Must offer the kidney and pancreas according to classifications 1 – 4 in Table 11-5 (donors < 50 years with BMI < 30) and Table 11-6 (donors > 50 years or BMI > 30)
- After classification 4, the OPO may either:
    - Continue to offer the kidney and pancreas according to the remaining classifications in Table 11-5 and Table 11-6
    - Offer the pancreas to pancreas and islet candidates (but not kidney-pancreas candidates) according to the remaining classifications and offer the kidney-to-kidney candidates according to kidney policy
    - May switch back and forth between above two options

Summary of discussion:

The Committee did not make any decisions.

A member noted that current policy prioritizes MOT over prior living donors even though prior living donors fall after highly sensitized candidates on the match run. Highly sensitized candidates might only get one offer and should be prioritized over MOT and prior living donors because they will typically get other opportunities.

A member commented that it is reasonable for the MOT Committee to discuss allocation sequences, but it is not within the purview of the MOT Committee to change kidney allocation. However, it would be reasonable for the MOT Committee to make recommendations to the Kidney Committee. Another member commented that it would be acceptable for the MOT Committee to address where sequence B candidates would fall within the safety net or to address how far down the single organ match run an OPO must go before offering to MOT candidates.

A member commented that if a kidney is not allocated with a pancreas, the pancreas is most likely to be discarded.

There were no additional comments or questions.

3. Values Prioritization Exercise (VPE): Design and Example Profiles

Staff provided an overview of a values prioritization exercise and how the attributes can help compare candidates.

Summary of Presentation:

Staff noted that the exercise would compare candidates that are ranked on different match runs, but not compare candidates that are ranked on the same match run since allocation order is already determined by the individual organ allocation system. There were eight attributes presented for potential inclusion in the VPE. Candidate profiles will be developed using attributes covered in current OPTN policy (e.g. prior living donor status would be included only in lung and kidney candidate profiles)

Staff provided an example of three candidates using the attributes organ registration, medical urgency, sensitization, candidate age group, prior living donor, alternate therapies, distance, and blood type. The example compared kidney alone, kidney-pancreas, heart-kidney candidates using the various attributes. Another example compared heart-lung, lung-kidney, and liver-lung candidates using the same attributes.

Summary of discussion:

The Committee did not make any decisions.

Staff asked for feedback on the attributes and cross-organ framework. A member commented that the pancreas stands out for not having many attributes. The Chair responded that kidney-pancreas will be part of the VPE.

A member commented that the exercise does not take into account the potential loss of a transplantable organ, such as a pancreas and multi-visceral combinations. A member responded that the committee should not spend too much time discussing the less common combinations and focus on prioritizing the combinations that OPOs must deal with every day. The Chair noted that the committee can figure out where multi-visceral candidates should fall once the committee identifies a draft allocation scheme.

Next Steps:

Staff will distribute a poll to committee members to address key prioritization questions.

4. Recognition of Outgoing Members

Staff and committee leadership recognized members rolling off the committee on June 30, 2024 and thanked them for their contributions.

Upcoming Meeting

- July 10, 2024

Attendance

- **Committee Members**
    - Lisa Stocks Chair)
    - Marie Budev
    - Vincent Casingal
    - Chris Curran
    - Alejandro Diez
    - Alden Doyle
    - Rachel Engen
    - Jonathan Fridell
    - Shelley Hall
    - Kenny Laferriere
    - Nicole Turgeon
- **HRSA Representatives**
    - Jim Bowman
- **SRTR Staff**
    - Katie Audette
    - Jon Miller
- **UNOS Staff**
    - **Meghan McDermott**
    - James Alcorn
    - Jessica Higgins
    - Robert Hunter
    - Sara Langham
    - Meghan McDermott
    - Sarah Roache
    - Laura Schmitt
    - Kaitlin Swanner
    - Suan Tlusty
- **Others**
    - Shunji Nagai
    - Erica Lease