OPTN Organ Procurement Organization Committee Multi-Organ Policy Review Workgroup Meeting Summary May 29, 2020 Conference Call

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Introduction

The OPTN Multi-Organ Policy Review Workgroup (the Workgroup) met via Citrix GoToTraining teleconference on 05/29/2020 to discuss the following agenda items:

- 1. Recap of 4/15 Meeting
- 2. Data Review
- 3. Next Steps

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

1. Recap of 4/15 Meeting

The Workgroup chair reviewed the decisions made during the Workgroup's previous meeting:

- Heart-liver
 - Allocate to 500 NM to align with heart policy
- Lung-liver
 - o Prioritize LAS greater than 35 instead of 45

Summary of discussion:

No discussion.

2. Data Review

The Workgroup reviewed the results from their data request:

- Liver Waitlist Mortality
- Heart Waitlist Mortality
- Lung Waitlist Mortality
- Heart and Liver Candidate Status at Time of MOT Transplant
- Lung and Liver Candidate Status at Time of MOT Transplant

Summary of discussion:

Waitlist Mortality for Liver, Heart, and Lung Candidates

UNOS Research staff presented data illustrating the waitlist mortality for liver, heart, and lung candidates. This data showed that waitlist mortality increased as MELD scores, heart statuses, or LAS increased.¹

^{1, 2, 3} Toll, Alice. UNOS Research, 2020 OPTN data

Heart and Liver Candidate Status at Time of MOT Transplant

UNOS Research staff presented data illustrating the status of heart-liver candidates at the time of MOT transplant from 2016-2019. Prior to the 2018, implementation of modifications to adult heart statuses, most heart-liver MOT recipients fell into Heart Status 1A. In 2019, most heart-liver MOT recipients were adult heart Status 2. In the past 4 years, only one heart-liver MOT recipient has had liver Status 1B. The maximum MELD score observed was 31 in 2016. The MELD/PELD scores are skewed towards lower values, especially in 2019.²

A Workgroup member inquired whether United Network for Organ Sharing (UNOS) would know how many recipients asked for exceptions on their model for end-stage liver disease (MELD) score. UNOS support staff stated that they didn't have this information.

Lung and Liver Candidate at Time of MOT Transplant

UNOS Research staff presented data illustrating the status of lung-liver candidates at the time of MOT transplant from 2016-2019. All lung-liver MOT recipients age 12 and older had a LAS score of at least 30 in the past 4 years. In 2018 and 2019, at least half of the recipient has an LAS score of at least 50. The liver scores for these recipients are more sporadic. The highest score observed was a PELD 40 for a pediatric patient in 2016. In the adult population, the highest observed were five MELD 35 (one in 2016, four in 2018).³

A Workgroup member inquired whether the data showed MELD scores or MELD exception scores. UNOS support staff explained that the data shows allocation scores instead of lab scores, so it could include exception scores.

A Workgroup member explained that most of the recipients they list for a lung and liver are listed with an exception score that is justified because most of the candidates are sicker. The member mentioned that MELD scores are more reflective of an exception that was granted.

A Workgroup member stated that the waitlist mortality starts to change when the lung allocation score (LAS) is between 35 and 40. Another member stated that a candidate is starting to get sicker with a LAS of 35. A member mentioned that lung candidates have multiple diseases with different clinical courses; therefore, LAS is also skewed based on disease. For example, patients with chronic obstructive pulmonary disease may have poor quality of life and have advanced symptoms, but they don't reach a LAS of 70 very easily.

A Workgroup member inquired about the wide bar for heart Status 1 candidates, shown on the heart LAS and waitlist mortality graph. UNOS support staff explained that the bar represents a large confidence interval due to very few candidates falling into the Status 1 category or their short length of time being categorized as Status 1.

A Workgroup member noted that there doesn't seem to be a large confidence interval for Status 1 liver candidates. UNOS staff explained that the liver data didn't include confidence intervals and that the analysis was different because the data was being pulled from different reports that have already been done, such as annual data reports and monitoring reports specific to policy.

A Workgroup member inquired about gathering more granular data on liver MELD scores. The member noted that there's a big range of MELD scores in the table and questioned whether the challenge is that some are MELD exception scores and it's hard to really look at that group's mortality. It was explained that it can't be assumed these MELD groupings would have the same mortality; i.e., a candidate with a MELD score of 16 would have a different mortality rate than a candidate with a MELD score of 33 even though they are both in the same grouping.

Workgroup members agreed that it would be helpful to see the liver MELD scores in more granular groups in order to understand at which time candidates are getting transplanted or dropping off of the waitlist.

A Workgroup member inquired about how MELD exception scores are used with heart transplant candidates. A member explained that heart transplant candidates usually have low MELD scores, so the decision is usually left to the heart team in order to select a donor. It was also noted that the heart usually pulls the liver so physicians don't apply for an exception score.

A Workgroup member mentioned that lungs don't usually pull the liver, so that's why physicians apply for an exception. The exception depends on the underlying disease of the patient. For example, the liver exception score request for cystic fibrosis patients is usually closer to 20-23.

A Workgroup member expressed concern about the priorities that had been laid out in the Workgroup's previous meeting. The member inquired whether livers should be allocated to sicker patients before they are allocated to multi-visceral patients. UNOS support staff explained that the Workgroup is trying to avoid taking livers away from potential Status 1 liver patients.

A Workgroup member inquired about where the most transplants are happening: is it when there are no heart Status 1, 2, or 3 candidates, and no liver Status 1A, 1B, or MELD greater than 35 candidates? UNOS support staff confirmed that this is when most transplants occur and the member suggested it would be beneficial to analyze more data regarding this group of recipients.

A Workgroup member expressed concern about policy language preventing candidates with a MELD/PELD of less than 15 and adult heart Status 2 from getting transplants. The member suggested more data on these candidates.

A Workgroup member cautioned the Workgroup about creating complicated MOT policies for the relatively small number of candidates. The member reminded the Workgroup that they are trying to create a policy that is easy to understand since the current policy is not clear.

Final decisions

A Workgroup member inquired about how long it would take to get additional data. UNOS support staff stated that it would take about a month; so, if the Workgroup continues to meet monthly, the data might be ready by the next meeting.

A Workgroup member suggested that it would be helpful to look at the distance thresholds of transplant recipients.

Another Workgroup member also mentioned examining heart allocation and the classifications that must be followed. It was suggested that these classifications could be followed for heart MOT's instead of picking a single distance. However, a member stated that the Workgroup is trying to replace donation service area (DSA) with a reasonable distance, not a national distance.

A Workgroup member also expressed concern about the heart pulling the liver for MOT candidates because the cardiac disease is affecting the liver. The member explained that the thoracic organ listing doesn't give the liver listing any automatic exceptions. A member mentioned that, from the liver listing exception guideline, the liver candidate may get a median MELD score at transplant minus 3. A member suggested granting them standard exception since it may help candidates get transplanted.

3. Next Steps

The Workgroup discussed the following next steps:

- Continue discussion of LAS, heart statuses, and heart classifications
- Reach out to Liver and Intestinal Organ Transplantation Committee to get their feedback on the current direction of the project
- Begin discussion on heart-kidney

Upcoming Meetings

• June 29, 2020 (teleconference)