OPTN Ad Hoc Multi-Organ Transplantation Committee Meeting Summary September 7, 2021 Conference Call

Charles Alexander, RN, MSN, MBA, CPTC, Chair

Introduction

The Ad Hoc Multi-Organ Transplantation Committee met via Citrix GoToMeeting teleconference on 09/07/2021 to discuss the following agenda items:

1. Follow-up items from 8/16: Eligibility Criteria
2. Follow-up items from 8/16: Safety Net

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

1. Follow-up items from 8/16: Eligibility Criteria

UNOS staff followed up on the remaining eligibility criteria discussion from the August 16 MOT Committee meeting.

Data summary:

Heart-Kidney Consensus Conference Recommendation 1: Expand criteria for CKD diagnosis to include candidates with GFR less than or equal to 44mL/min and persistent proteinuria >0.5 g/day in the presence of stable hemodynamics

Heart-Kidney Consensus Conference Recommendation 2: Increase GFR threshold for sustain AKI diagnosis from 25 mL/min to 30 mL/min

Summary of discussion:

Heart-Kidney Recommendation 1

A member expressed concern that with 97,000 patients waiting for kidneys this proposal does not advocate for kidney alone patients whom have been on dialysis for seven to ten years. This member emphasized that the data from the ISHLT consensus conference on heart-kidney transplantation was not from randomized clinical studies and it was unclear if the patients in the study were in imminent need of a kidney for their survival. Members felt that more data was necessary to support increasing the qualifying GFR to 44 and modeling needed to be done to better understand how this change would impact the kidney alone wait list. A member echoed that the purpose of the safety net is to allow an avenue for those individuals to receive a second organ. By staying consistent with the Simultaneous Liver-Kidney (SLK) policy as the starting point, it gives the OPTN an opportunity to see if they made the correct decision and adjust as necessary.

Heart-Kidney Recommendation 2

One member suggested staying with 25 while another member highlighted the immunological difference between hearts and livers potentially needing a different policy. A member noted that in this circumstance, highly sensitized patients would have a higher priority but there was concern that reducing the number of patients who are exposed to a second donor could have a greater benefit for

heart recipients than liver recipients. A member stated that moving to a GFR of 44 is too high but that a GFR of 30 could be reasonable if it removes some patients from the safety net. A member pushed back that these decisions did not make scientific or medical sense for heart recipients and anticipated a lot of pushback from the heart community.

A member inquired if it is possible to see data on what GFR heart recipients were listed as at the time of transplant. A representative from UNOS Research responded that the waitlist only indicates if a patient qualifies based on their GFR and not what that GFR is, but UNOS staff will double check and confirm at the next meeting.

Next steps:

UNOS staff will be following up with the OPTN Histocompatibility Committee on September 14 to discuss immunological differences between liver and heart transplantation. UNOS staff will also be following up with the OPTN Heart Transplantation Committee on September 21 to discuss the removal of metabolic disease.

2. Follow-up items from 8/16: Safety Net

UNOS staff followed up on the remaining safety net discussion from the August 16 MOT Committee meeting.

Data summary:

Heart-Kidney Consensus Conference Recommendation 3: Allow eligibility for safety net to start 30 days after heart transplant rather than 60 days after heart transplant

Heart-Kidney Consensus Conference Recommendation 4: Increase safety net GFR threshold from CrCl or GFR ≤ 20 mL/min to CrCl or GFR ≤ 30 mL/min

Summary of discussion:

Heart Kidney Recommendation 3

For historic reference, a member shared that when developing the SLK policy there was consensus between the OPTN Kidney Transplantation Committee and the community that felt that 30 days was an inadequate timeframe to determine if the kidney would recover and went with 60 days instead. A member expressed concern over having both a strict eligibility criteria and a strict safety net. A member was hesitant to utilize the safety net too early in the process if the patients have a higher comorbidity and risk of mortality. A member inquired about the evidence that indicated 30 days was imperative for kidney transplant, noting that hemodynamically there is a lot of recovery occurring at this time and a possibility that the kidney could regain function if given more time. Furthermore, a member noted that programs often do not declare end stage kidney failure until 6-8 weeks into dialysis.

Alternatively, in heart transplant there is a greater concern about rejection and required more medical management to reduce rejection, which can lead to a vicious cycle if not appropriately allocated. There was pushback that since livers and hearts are different hemodynamically, immunologically, and disease etiology wise that the same policy would not work for both organs.

In all, a member suggested that 6 weeks might be the sweet spot between 30 and 60 days. A member suggested a consistent safety net window across organs to reduce confusion and pushback. UNOS staff suggested posing the 6 week, 42 day safety net window question during public comment and adjust based on community feedback.

Heart Kidney Recommendation 4

Members were concerned that there would be a lot of pushback from the kidney community and it would be important to keep the GFR consistent with what it is for kidney alone patients. Once the patient has received the heart transplant, they must meet the standard kidney criteria to receive the transplant. A member suggested potentially allowing someone to be eligible for the safety net with a GFR of 30 but not transplanting them until their GFR drops to 20 or below. Ultimately, there was support from the majority of members to keep the GFR at 20.

Lung-Kidney Safety Net Eligibility

The OPTN Lung Transplantation Committee felt that the safety net needed to extend because it often takes a year to stabilize a patient after lung transplant before they could be able to receive the second organ. In addition to concern over the limited supply of kidneys, a member noted that the purpose of the safety net is to catch the patients who were missed by multi-organ transplant and that should be able to be done within one year. While the patient does not need to receive the transplant in that one-year period, it is reasonable to identify the individuals who would need the second organ and qualify for it. The consensus from members was keeping the safety net consistent with the SLK policy.

Safety Net for Pediatric Candidates

A member noted that Sequence B kidneys are very hard to come by for kidney alone patients because they are allocating to multi-organ patients and that it may not be the best way to match organs to these patients. A member noted that the scope of this project is not to determine when to allocate to multi-organ versus single organ patients, but that the safety net sequence eligibility could be amended if there is a need. UNOS staff reminded the group that the allocation sequences will be reviewed by the OPTN Kidney and Pancreas Transplantation Committees when they develop their continuous distribution framework.

A member inquired if UNOS Research could provide more insight about which sequence kidneys are going to safety net patients and adjust from there if necessary. A member also requested to identify the characteristics of the recipient of the safety net kidney.

Qualifying for safety net after kidney transplant

Members were supportive of remaining consistent with the SLK policy.

Next steps:

UNOS Research staff will draft a formal data request for the heart-kidney GFR information and safety net sequencing. The Committee will revisit outstanding questions regarding metabolic disease during the next meeting to finalize eligibility criteria.

Upcoming Meetings

- September 20, 2021
- October 12, 2021
- November 1, 2021
- November 22, 2021

Attendance

- **Committee Members**
    - Alden Doyle
    - Alejandro Diez
    - Christopher Curran
    - Evelyn Hsu
    - James Sharrock
    - Jennifer Prinz
    - Kurt Shutterly
    - Marie Budev
    - Molly McCarthy
    - Nicole Turgeon
    - Oyedolamu Olaitan
    - Sandra Amaral
    - Shelley Hall
    - Stacy McKean
    - Vincent Casingal
- **HRSA Representatives**
    - Jim Bowman
- **SRTR Staff**
    - Jon Snyder
    - Katie Audette
- **UNOS Staff**
    - Amber Wilk
    - Ben Wolford
    - Elizabeth Miler
    - Eric Messick
    - Kaitlin Swanner
    - Kayla Temple
    - Krissy Laurie
    - Laura Schmitt
    - Leah Slife
    - Lindsay Larkin
    - Matt Prentice
    - Melissa Lane
    - Nicole Benjamin
    - Rebecca Goff
    - Sara Rose Wells
    - Susan Tlusty