OPTN Ad Hoc Multi-Organ Transplantation Committee
Meeting Summary
August 16, 2021
Conference Call

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

Introduction

The Ad Hoc Multi-Organ Transplantation (MOT) Committee met via Citrix GoToMeeting teleconference on 08/16/2021 to discuss the following agenda items:

1. Project Plan
2. Eligibility Criteria
3. Safety Net
4. Next Steps and Closing Remarks

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

1. Project Plan

UNOS staff provided an overview of the project scope, following its approval by the Policy Oversight Committee (POC) on 8/11/2021, and the drafted project map.

2. Eligibility Criteria

UNOS staff provided a recap of the July 26, 2021 MOT meeting where the group reviewed feedback from the Data Advisory, Heart, Kidney, and Lung Committees. UNOS staff shared the proposed eligibility criteria for Simultaneous Lung-Kidney (SLuK) and Simultaneous Heart-Kidney (SHK).

Data summary:

The SLuK Eligibility Criteria reflects the Simultaneous Liver-Kidney (SLK) policy but replaces liver with lung, where necessary, and removes the metabolic disease category.

The SHK Eligibility Criteria has two options. Option 1 reflects the SLK policy but replaces liver with heart, where necessary, and removes the metabolic disease category. Option 2 reflects the recommendations made by the 2019 Consensus Conference[1] and removes the metabolic disease category.

Summary of discussion:

Simultaneous Lung-Kidney

A member expressed concern regarding a comment made in a previous meeting about the physiological difference between thoracic and abdominal organs and questioned if consistent policy would be the best policy for these populations. A member said that thoracic organs are different in that renal recovery is less likely following a lung-alone transplant, so it may be appropriate for the lung-kidney criteria to be more judicious. Alternatively, when developing the SLK policy, there were a percentage of patients who were expected to recover kidney function after liver transplant. Ultimately, the member

[1] Jon Kobashigawa, Darshana M. Dadhania, Maryjane Farr, et al., "Consensus conference on heart-kidney transplantation," *American Journal of Transplantation* 00 (2021): 1-9, DOI: 10.1111/ajt.16512.

urged that this eligibility criterion should encompass the need of patients in a manner that reflects similar policies. Multiple members voiced their support for a consistent policy.

The HRSA representative informed the Committee of a rare metabolic lung condition, Alpha 1 Antitrypsin Deficiency, which can appear in pediatric candidates and suggested further consideration from the Lung Committee before finalizing the removal of metabolic disease.

Simultaneous Heart-Kidney

Multiple members voiced their support for Option 1. The concerns for Option 2 were potentially subjective language, the necessity for more data to justify the difference in eligibility criteria, and the improved outcomes observed in kidney after heart recipients compared to kidney after lung recipients. A member suggested the possibility of including 'previous single organ transplant recipient' as an attribute in the continuous distribution framework. A member added that with the safety net, the patients who need both organs would be able to be eligible for them.

Based on member's feedback, the Chair suggested proceeding with Option 1 in the policy proposal and then revise it as needed from public comment feedback. A representative from the OPTN Heart Transplantation Committee agreed with this plan to pursue Option 1 and reconsider if there is strong pushback from the community.

Next steps:

UNOS staff will check in with the Heart and Lung Committees regarding the metabolic disease diagnosis category.

3. Safety Net

UNOS staff provided a recap of the SLK safety net policy 8.5.G *Prioritization for Liver Recipients on the Kidney Waiting List.* Committee members reviewed safety net proposals for kidney after heart and kidney after lung allocation and discussed a variety of general safety net questions.

Data summary:

The proposed Lung-Kidney Safety Net reflects the SLK policy but replaces liver with lung, where necessary.

The proposed Heart-Kidney Safety Net has two options. Option 1 reflects the SLK policy but replaces liver with heart, where necessary. Option 2 reflects the recommendations made by the 2019 Consensus Conference.[2] This option reduces the eligibility window's opening from 60 days to 30 days following the heart-alone transplant and adds 'for six weeks' to the criteria "CrCl of GFR less than or equal to 20 mL/min."

Summary of discussion:

Lung-Kidney Safety Net

Multiple members voiced their support for this proposal and in favor of consistent policy. A member added that the immunosuppression of thoracic organs can be slightly different from livers but this issue tends to be more relevant in patients with acute disease and not chronic kidney disease (CKD). A member noted that as UNOS collects data on the policy the committee could modify the safety net as needed. Since no sufficient data existed to steer the Committee in an alternative direction, the members were in favor of following the precedent of the SLK policy.

[2] *Ibid.*

Heart-Kidney Safety Net

A representative for the OPTN Heart Transplantation Committee suggested that the consensus conference recommendations expanded the safety net eligibility window to 30 days following heart transplant because if the patient is on dialysis for a month then the kidneys are unlikely to recover. There was concern that if a patient missed the cut off by 1 or 2 points to qualify then they would have an extremely poor, long term, quality of life. UNOS staff replied that the patients who do not meet the safety net criteria could still register for a kidney transplant; they just would not receive the additional safety net priority.

The representative for the OPTN Kidney Transplantation Committee confirmed that if the patient's GFR was not below 20 mL/min then they would not receive any priority and transplantation would likely take years. This member did not feel that they could support a patient who has received a heart transplant previously to have priority points over another patient with the exact same GFR without additional data supporting why this is necessary.

In order to make a more informed decision, a member expressed the need for additional data points. This data included outcomes for lung alone and heart alone transplants, what renal recovery looks like for lung alone and heart alone recipients, and the percentage of lung alone and heart alone patients that go on to have renal failure after transplant. If this data depicted that lung alone or heart alone patients with a GFR of 30 did worse after single organ transplant, then the member would be more inclined to support Option 2.

A member noted that while the main difference between Option 1 and Option 2 are the lengths of time, the greater question is if a GFR of 20 mL/min is reasonable or if it should be 30 mL/min. A UNOS staff member from the Research Department shared that this data exists for patients who followed up after their transplants and patients who are subsequently listed for a kidney transplant. UNOS does collect data on creatinine clearance at follow up for heart alone and lung alone patients.

A member inquired why the GFR requirements for SHK is 30 mL/min but the safety net requirement is 20 mL/min. A member responded that renal function could decrease after multi-organ transplant, mainly due to calcineurin toxicity, which would prioritize CKD patients who did not improve renal function after single organ transplant. By utilizing the requirements in Option 1, it places the patient on the same comparison as kidney alone patients to allow for a more equitable access, since kidney alone candidates must either be on dialysis of have a GFR of 20 mL/min or less to begin accruing waiting time. Another member added that calculating GFR as an MOT patient can be very challenging so once organ function has returned for first organ it allows the patient to return to the existing criteria for transplant of the second one.

General Safety Net Questions and Discussion

UNOS staff posed the question should the Committee restrict the safety net priority in Sequence B to candidates with Estimated Post Transplant Survival Score (EPTS) <20.A member countered that the EPTS includes a built in disadvantage by factoring if a patient is a prior organ transplant recipient. Members voiced support for a policy that was consistent with what was already in place for SLK, with additional priority given to pediatric patients. Members added that pediatric candidates should already have priority that is greater than the safety net, but if that were not the case, the Committee would be in favor of adding that to the existing and upcoming safety net policies.

UNOS staff inquired if the heart and lung patients should be sorted the same way as other multi-organ kidney combination patients as be OPTN *Policy 8.5.C?* A member supported sticking to the existing kidney points because there is insufficient data to demonstrate a necessity for an alternative policy. A

member clarified that the wait time for a safety net kidney begins when a candidate registers for the kidney waitlist and not at the time they received their primary organ transplant.

If a liver recipient receives a kidney via safety net priority and ends up needing another kidney, they could return to the safety net if they do not quality for kidney waiting time reinstatement. UNOS staff asked if this policy should also apply to heart and lung recipients? Members expressed concern about prioritizing these patients over kidney alone patients who also lost their kidney graft and have to be relisted. A member elaborated that when transplanted as an SLK patient, a patient would be eligible for a safety net kidney if their graft failure was caused by primary non-function. Due to time constraints, the Chair suggested pausing this conversation until the next Committee meeting.

4. Next Steps and Closing Remarks

UNOS staff will compile additional information on Option 2 for the Heart-Kidney safety net to better inform the Committee if the GFR threshold needs to change from 20 mL/min. Members would like to discuss further the patient eligibility for a second safety net transplant.

Upcoming Meetings

- September 7, 2021
- September 20, 2021
- October 12, 2021
- November 1, 2021
- November 22, 2021

Attendance

- **Committee Members**
  - Charles Alexander
  - Christopher Curran
  - Evelyn Hsu
  - Garrett Erdle
  - James Pomposelli
  - James Sharrock
  - Jennifer Prinz
  - Kurt Shutterly
  - Nicole Turgeon
  - Oyedolamu Olaitan
  - Stacy McKean
  - Vincent Casingal
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Jon Miller
  - Jon Snyder
  - Katie Audette
  - Nick Salkowski
- **UNOS Staff**
  - Amber Wilk
  - Eric Messick
  - Holly Sobczak
  - Kaitlin Swanner
  - Laura Schmitt
  - Leah Slife
  - Matthew Prentice
  - Melissa Lane
  - Nicole Benjamin
  - Ross Walton
  - Sarah Konigsburg
  - Sara Rose Wells
- **Other Attendees**
  - Adrian Lawrence
  - Omar Moussa
  - Richard Daly