OPTN Heart Transplantation Committee
Meeting Summary
July 20, 2021
Conference Call

Shelley Hall, MD, Chair
Richard Daly, MD, Vice Chair

Introduction

The Committee met via Citrix GoToMeeting teleconference on 07/20/2021 to discuss the following agenda items:

1. Regional Meeting Schedule
2. Heart-Kidney and Lung-Kidney Eligibility Criteria and Safety Net
3. Donor Service Area (DSA) one-year monitoring report

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

1. Regional Meeting Schedule

Summary of discussion:

UNOS staff shared the regional meeting dates and encouraged members to attend. The meetings will be held in-person this cycle. The Heart Transplantation Committee will present the following two proposals during regional meetings:

- Amend status extension requirements in adult heart allocation policy
- Report primary graft dysfunction (PGD) in heart transplant recipients

Regional representatives are expected to read the full proposal, present at their regional meeting, and share the feedback received with the Committee. Meetings to help the regional representatives prepare are being scheduled. UNOS staff will provide slides and speaker notes in advance of the trainings and will be on the regional meeting calls to help answer any questions as necessary.

Regional meeting agendas, additional information, and links to register are available on the OPTN website.

2. Heart-Kidney and Lung-Kidney Eligibility Criteria and Safety Net

The Chair provided an overview of the work being completed by the Ad Hoc Multi-Organ Transplantation (MOT) Committee and asked the members for their initial feedback.

Summary of discussion:

The recently formed MOT Committee is charged with developing and proposing allocation policies that address multiple organ groups as well as the practice of multi-organ allocation. The MOT Committee is also tasked with ensuring proposed policies are in alignment with the OPTN Final Rule and the transition of organ allocation to a continuous distribution framework. Members include representatives from all organ specific committees as well as many other OPTN committees.

The MOT Committee is aiming to propose eligibility criteria and safety net policies for heart-kidney and lung-kidney during the January 2022 public comment cycle. Eligibility criteria and safety net policies for heart-lung, lung-liver, and liver-heart will be proposed during the January 2023 public comment cycle.

The Chair shared that eligibility criteria establishes the qualifying medical conditions required for a candidate to receive a second organ. A safety net establishes priority for patients who receive a single organ but qualify for a second organ shortly after transplant.

The Chair provided an overview of the simultaneous liver-kidney (SLK) eligibility criteria and safety net policies currently implemented. She commented that there is no policy currently implemented that provides eligibility criteria relating to kidney disease severity for candidates listed for both kidney and heart. Currently, when a kidney is offered with a heart or lung, allocation is based on the severity of the candidate's heart or lung disease.

In 2020, there were 290 heart-kidney transplants. The Chair shared that this number may be increasing due to sicker patients receiving heart transplants who may also experience renal injury. Available studies support Simultaneous Heart-Kidney (SHK) Transplantation for certain patients. The Chair commented that if a heart candidate is on dialysis prior to transplant, they may not do as well with a single heart transplant. SHK have similar survival rates to heart alone recipients and there is improved survival for SHK over heart alone recipients who have renal failure. Additionally, dialysis after heart transplant is associated with increase in death or morbidity.

In 2019, a consensus conference was held to develop recommendation for SHK eligibility criteria and safety net policies. These recommendations include setting eligibility criteria so patients with a glomerular filtration rate (GFR) under 30 may be considered for SHK. If the candidate has a GFR of 30-44, then additional evidence of chronic kidney disease (CKD) is required. Recommendations for safety net criteria included a GFR of 45-59 or, for heart recipients on chronic dialysis, the requirement of persistent GFR equal to or below 20.

The Chair shared a comparison of SLK criteria and the SHK consensus conference recommendation. The MOT Committee is proposing using the SLK eligibility criteria and safety net as a starting point for SHK and simultaneous lung-kidney transplant (SLuK). The Chair asked the members if there were any concerns with this approach.

A member raised a concern about using the SLK safety net as a framework as a lot of heart recipients are going to have primary graft dysfunction (PGD) with poor cardiac output and kidney failure. The member recommended including hemodynamic criteria to exclude recipients with poor cardiac output as they may be unlikely to have good kidney transplant outcomes.

The Vice Chair questioned if the safety net applies to any heart recipient who has post-operative renal failure. UNOS staff shared that for SLK, the intent was to capture patients who had renal issues prior to the liver transplant but existing policy is not prohibitive of patients who may develop renal failure following liver transplant within a year of the liver transplant. The Chair commented that the intent of the safety net policy should be clarified. A member agreed and commented that the verbiage of "safety net" could also be reconsidered.

The Chair asked if the members had any issues with the SLK GFR numbers proposed for SHK. A member questioned if patients will need to qualify every 7 days and raised a concern about the related reporting and data entry. The Chair commented that patients in the intensive care unit with acute kidney injury and heart failure are likely to receive weekly labs.

A member questioned if more specificity is needed around how GFR is calculated. UNOS staff confirmed that it is not currently specified.

The members discussed if the SLK safety net criteria or the consensus conference recommendations should be applied to SHK. The members considered the SLK criteria as being more restrictive than the consensus conference recommendations. When reviewing the SLK criteria, a member recommended requiring more than one measure of less than 20 for calculated creatinine clearance (CrCl) or GFR to exclude patients that only have one isolated occurrence of these lab values. The Vice Chair recommended considering the recipient's age when assessing CrCl or GFR. A member recommended reviewing heart and heart-kidney patients with GFR 30-60 to compare outcomes to assess if these SHK patients have better outcomes.

A member commented that performing a SHK rather than having a second transplant operation for a kidney under the safety net policy would help to limit the number of donors and thereby reduce antigen exposure for the recipient. She suggested applying the less restrictive SHK eligibility criteria recommended in the consensus conference. The Chair agreed that this increased sensitization does add another risk for the success of the kidney transplant.

A member recommended that the SHK eligibility criteria include patients with established GFR less than 45 as well as patients with established GRF of 45-60 with firm evidence of chronic kidney disease (CKD).

Another member recommended using the consensus statement criteria as a lot of work went into it and it is still current. She noted the criteria could be made stricter based on community input during public comment.

UNOS staff asked if the range for the SHK safety net eligibility should be 60-365 days post-transplant to be consistent with the current SLK safety net or 30-365 days post-transplant to be consistent with the consensus conference recommendation. The Chair agreed with using the consensus conference recommendation of 30-365 days post-transplant.

3. Donor Service Area (DSA) one-year monitoring report

UNOS Research staff provided an overview of the removal of DSA from heart allocation 1 year monitoring report. A full report is available to the members on the Committee SharePoint page.

Summary of discussion:

UNOS Research staff shared that DSA was removed from heart allocation on January 9, 2020 in order to increase equity and access to transplant. The two eras compared in the report consist of one year following implementation (January 9, 2020-January 8, 2021) and the year prior to implementation (January 9, 2019- January 8, 2020).

Waiting List

- There was a slight decrease in proportion of candidates listed as Status 4 and slight increase in the proportion of candidates listed as Status 2 post-implementation
- Waitlist additions by region did not vary significantly
- The proportion of candidates removed from the waitlist for death or being too sick to transplant increased slightly for pediatric Status 1A, decreased slightly for pediatric Status 1B, and remained the same for pediatric Status 2 post-implementation
- The proportion of candidates removed from the waitlist for death or being too sick to transplant increased slightly for adult statuses 1 and 5 post-implementation
- There was no significant difference in waitlist mortality rates post-implementation

Transplant

- There was a larger proportion of adults transplanted at Status 4 and a decrease in the proportion of adults transplanted at Status 3 post-implementation
- There was a slight decrease in hearts traveling 250-500 nautical miles (NM) and a small increase in hearts traveling less than 250 NM post-implementation
- There was a decrease in sharing within the DSA and an increase in regional sharing post-implementation
- The median distance for travel decreased by 7 NM post-implementation
- Total ischemic time remained similar between the two eras
- There was a significant increase in transplant rates overall post-implementation

Additional outcomes

- Utilization and discard rates remained similar between eras
- There was no significant decrease in post-transplant six-month patient survival between eras

The members commented that transplant rates have increased and survival has not changed which is a good outcome of this policy change.

Upcoming Meetings

- August 17, 2021
- September 21, 2021
- October 6, 2021 (In-Person)
- November 16, 2021

Attendance

- **Committee Members**
  - Amrut Ambardekar
  - Cindy Martin
  - Cristina Smith
  - David Baran
  - JD Menteer
  - Jennifer Carapellucci
  - Jonah Odim
  - Jose Garcia
  - Kelly Newlin
  - Michael Kwan
  - Rocky Daly
  - Shelley Hall
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Katie Audette
  - Yoon Son Ahn
- **UNOS Staff**
  - Chris Reilly
  - Eric Messick
  - Kaitlin Swanner
  - Keighly Bradbrook
  - Laura Schmitt
  - Leah Slife
  - Samantha Weiss
  - Sara Rose Wells
  - Sarah Konigsburg
  - Susan Tlusty