

OPTN Heart Transplantation Committee

Meeting Summary

March 15, 2022

Conference Call

Shelley Hall, MD, Chair
Rocky Daly, MD, Vice Chair

Introduction

The Heart Transplantation Committee met via Citrix GoToMeeting teleconference on 03/15/2022 to discuss the following agenda items:

1. April 19 Committee In Person Meeting
2. Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation presentation

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

1. April 19 Committee In Person Meeting

Staff reviewed the general information for the Committee's in person meeting in April. More specific information will be provided as the meeting draws closer.

Summary of discussion:

Members inquired about booking their travel and accommodations. UNOS Meeting Partners will reach out to members directly on Monday, March 21. If members have not heard from them at that time, they are encouraged to reach out to the Committee support staff.

A member inquired about social distancing guidelines. Members were informed that the OPTN protocol approved by the OPTN Executive Committee in December 2021 will be in place for the April 19th meeting. These protocol could change if the Executive Committee decides to review its policy. UNOS staff will communicate social distancing and mask guidance as the meeting nears.

Next steps:

UNOS Meeting Partners will reach out directly to members to book travel. Members should contact Heart Committee staff if they have any questions about the meeting.

2. Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation

Dr. Alden Doyle, MD, MPH, the Chair of the OPTN Ad Hoc Multi-Organ Transplantation (MOT) Committee, presented the public comment proposal *Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation*. This proposal is largely modeled after the eligibility criteria and safety net utilized in the Simultaneous Liver-Kidney (SLK) proposal.

Summary of discussion:

Committee members were grateful for the opportunity to comment on the Ad Hoc MOT Committee's proposal. In summary, members expressed concerns regarding three specific aspects of the proposal. First, restricting access to Simultaneous Heart-Kidney (SHK) transplantation to adult heart statuses 1, 2, and 3 is extremely detrimental to the health of the adult heart status 4 candidates who have ventricular

assistance devices (VAD). According to the Committee members, transplant programs will essentially have to let the health of their status 4 candidates worsen, in hopes that the candidate qualifies for heart statuses 1, 2, or 3.

Second, the Committee was also concerned with the SHK eligibility requirement that a candidate with acute kidney injury must receive dialysis at least once a week for the prior six consecutive weeks or have an estimate CrCL or GFR less than or equal to 25 mL/min for the same period of time. The Committee members agreed that requiring six weeks of dialysis to qualify for SHK for a candidate who has an acute kidney injury and who is supported by a temporary mechanical device is a long time and puts the patient at risk. This puts the patient and the transplant program in a precarious situation around making those difficult decisions.

The members' third point addressed access to listing on the waitlist. Committee members discussed the findings from several peer-reviewed journals suggesting that heart recipients who require dialysis following transplant have significantly higher 30 day and one-year mortality than recipients who did not require dialysis. Several Committee members stated that a heart transplant program is unlikely to list a patient when it is likely that the patient will end up on dialysis following the heart transplant because of the mortality associated with post-transplant dialysis.

The consensus of the Committee was that the proposal would be greatly improved by expanding SHK eligibility to adult heart status 4 candidates who are receiving dialysis. The members also agreed that the proposed safety net language could improve access to kidneys for heart transplant recipients, in part because the safety net policy does not impose any restrictions on an individual's adult heart status.

The following is a more detailed account of the Committee's discussion regarding the proposal.

A member noted that the rationale for developing eligibility is very sound and a huge step forward. The member noted that, nonetheless, there is a large group of patients who experience acute kidney injury (AKI) whom would not be eligible for a heart-kidney transplant because the center either would not list them or the patient would not live six weeks after the qualifying GFR. The member suggested collecting some type of data that would capture this group of patients. The presenter responded that the purpose of the six week requirement is to provide time for patients to potentially recover renal function prior to doing a simultaneous transplant.

A member added that a second transplant has a larger immunologic impact on heart transplant candidates than liver recipients. The presenter responded that there is an immunologic advantage to receiving two organs from the same donor, but the literature and data do not show that the immunologic risk is unmanageable and should determine allocation. A member countered that often times heart recipients do not go on to receive a second organ in the 18 months after transplant, so there is less known about the immunologic impact of two organs from two donors on heart recipients.

A member expressed concern that the limitation of eligibility to patients who are statuses 1, 2, and 3 fully excludes all of the LVAD patients on dialysis that are listed as Status 4. This exclusion would force patients to become sicker and more at risk just to qualify for transplant. Throughout the presentation, multiple members echoed this sentiment and concern for Status 4 VAD patients on dialysis. The presenter noted that this feedback has been strongly shared by the Heart Chair in the MOT Committee meetings and by other members of the thoracic community during public comment. This feedback will be helpful to inform the proposal and balance the feeling from the kidney community that a lot of MOT patients pull kidneys from kidney alone patients. The member also noted that Status 5 is currently used to list heart-kidney patients and those patients would not be eligible for a heart-kidney offer under this eligibility criteria.

A member commented that a new journal article considers the mortality risk for patients who receive a heart transplant and end up on dialysis and noted the significantly higher mortality risk for heart patients compared to liver patients due to biological differences.¹ A member echoed this sentiment and added that oftentimes a center will not list a patient if they believe the patient will end up on dialysis after transplant of a heart alone, and that the data about such candidates is never collected. A member added that this would become an issue of access to heart transplant in general.

The presenter responded that the MOT Committee has approached this allocation challenge with the goal of being consistent with the SLK policy in framework and adapting when its clinically relevant. Some of the MOT Committee members stated that there is not enough clinical data or literature to pursue alternate options at this time, but they will review the safety net once it is implemented and revise it as necessary. A member replied that suggesting to review the policy again after implementation is insufficient and harms the patients who will be impacted by the policy upon implementation.

The Heart Committee Chair added that the safety net is a new concept to the thoracic community and the resistance was similarly felt by the Liver community during the development of SLK. The Chair added that when the heart allocation framework changes to continuous distribution, the hard boundaries of the statuses will be removed and the benefit of the safety net will be built in.

A question was raised about whether the MOT Committee had considered the impact on Black race access to kidneys, or whether modeling had been performed around the topic. The Committee member was told that the proposal is not using race as a factor.

A member asked why the MOT Committee did not consider additional qualifiers other than GFR. The presenter responded that GFR is an objective consideration and directly correlates to outcomes. There are alternatives but those are more subjective and not as closely correlated to outcomes.

The Heart Committee Chair stated that while SHK is increasing in quantity, the volume is still lower than the SLK population and the increased risks should warrant flexibility in eligibility criteria. A member suggested looking at data from 2015 to 2020 and analyze how many of those SHK recipients would not have been transplanted under the proposed policy. A member added that limiting the eligibility criteria could lead to creative medical care and an increase in exception requests in order to meet eligibility criteria.

UNOS staff added that statuses 4, 5, and 6 will not be ineligible to receive a SHK offer, but the organ procurement organization (OPO) would need to first go through statuses 1, 2, and 3 in the eligibility criteria before offering to patients in statuses 4, 5, 6. The Heart Chair countered that the kidney will be allocated through the kidney list first before the OPO considered offering an MOT to a heart candidate in statuses 4, 5, or 6. The Chair suggested including Status 4 patients on dialysis in the eligibility criteria of the MOT proposal.

Next steps:

UNOS staff will consolidate the feedback from today's discussion into the Committee's official public comment. Members are encouraged to submit their own public comments. Public comment will close on March 23.

¹ Satoshi Shoji et al., "Incidence and long-term outcome of heart transplantation patients who develop postoperative renal failure during dialysis," *The Journal of Heart and Lung Transplantation* 41, 3 (March 2022): 356-364. <https://doi.org/10.1016/j.healun.2021.11.017>.

3. Committee Activities and Other Business

The educational email subcommittee draft has been finalized. Communications has developed a draft of the email for the subcommittee to review before sending it out. During the February meeting, the Committee discussed the Medtronic letter. There is a draft email being worked on internally and will update the Committee with its progress. The Committee will receive an update on the Revise CAD/CAV project.

Committee members will receive information from UNOS Meeting Partners on Monday, March 21, about booking travel for the April in person meeting. Members are asked to email UNOS staff about which dinner options they would prefer, either an information gathering or a banquet style meal.

Upcoming Meetings

- April 19, 2022 – Chicago, IL
- May 17, 2022
- June 21, 2022

Attendance

- **Committee Members**
 - Shelley Hall, Chair
 - Rocky Daly, Vice Chair
 - Tariq Ahmad
 - Amrut Ambardekar
 - David Baran
 - Jennifer Carpellucci
 - Hannah Copeland
 - Jose Garcia
 - Michael Kwan
 - Cindy Martin
 - JD Menteer
 - Nader Moazami
 - Kelly Newlin
 - Jonah Odum
 - Fawwaz Shaw
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Yoon Son Ahn
 - Katie Audette
- **UNOS Staff**
 - Eric Messick
 - Keighly Bradbrook
 - Krissy Laurie
 - Janis Rosenberg
 - Laura Schmitt
 - Kaitlin Swanner
 - Ross Walton
 - Sara Rose Wells
- **Other Attendees**
 - Jen Cowger
 - Alden Doyle
 - Timothy Gong
 - Earl Lovell