

OPTN Ad Hoc Multi-Organ Transplantation Committee Meeting Summary June 21, 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 06/21/2021 to discuss the following agenda items:

- 1. OPTN Board Meeting Update
- 2. Heart-Kidney
- 3. Lung-Kidney
- 4. Next Steps

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

1. OPTN Board Meeting Update

UNOS staff updated the Committee on the decisions from the OPTN Board Meeting which impacted the work being done by this Committee. The Board approved the Organ Procurement Organizations (OPO) Committee's proposal *Clarify Multi-Organ Allocation Policy* with 34 in favor, 2 opposed, and 2 abstained. Discussions during the Board meeting expressed concern about certain patient populations being overlooked and the role of match run prioritization.

Summary of discussion:

The Chair identified the need to continue to provide greater guidance to OPOs on how to prioritize match runs. A member informed the group that the OPO Committee reviewed allocation options for specific multi-organ combinations and suggested reviewing the work that's already been done and utilize that analysis as the MOT Committee moved forward. A member echoed the previous statement and informed the group that the discussions the Board had aligned with some of the earlier work by the OPO Committee.

A member expressed concern that since multi-organ transplant outcomes do not factor into SRTR's transplant program performance monitoring, this may encourage transplant programs to consider multi-organ transplants over single organ transplants even if it is not 100% indicated. Members agreed with this concern. A member added that only a handful of transplant centers perform heart or lung multi-organ transplants and the data on multi-organ lung combinations is very weak. Reflecting on the Simultaneous Liver Kidney (SLK) policy, a member suggested more liberal use of safety net policies for multi-organ kidney combinations to help prevent unnecessary multi-organ transplants.

Another member identified the inability to compare mortality and morbidity risks across different organ systems, but the community is asking for these conversations and decisions. While comparing across organs can be like comparing apples to oranges, developing eligibility criteria and a safety net is the best plan forward for the Committee to start making some of those decisions.

A member highlighted the gap between kidney patients and other organ patients in end stage disease who do not have access to dialysis or an insurance mechanism to cover the financial impact. As the

heart allocation system has shifted towards prioritizing the most medically urgent patients who have more end organ dysfunction, it has become more difficult for surgeons to predict if patients will resume kidney function after transplantation resulting in an increase of simultaneous heart-kidney transplants.

A member suggested outlining a charter that indicates the Committee's priorities in a tiered manner (i.e. commit to reducing transplant mortality first then upholding equity) as a baseline to develop multiorgan allocation policies. The goal of developing a charter would be to avoid circular conversations and provide clarity on the principles of the policies. In addition to determining which recipients would benefit from single versus multi-organ transplant, a member suggested outlining which donors are optimal for multi-organ transplants.

The Chair praised the work of the SRTR in risk adjusting for single organ transplants and is hopeful that as the Committee develops multi-organ transplant policies the data collection and projection will continue to improve.

2. Heart-Kidney

Shelley Hall, the Chair of OPTN Heart Transplantation Committee and member of the MOT Committee, presented literature and data on Simultaneous Heart-Kidney Transplantation (SHK) and provided an overview of the 2019 Consensus Conference on SHK.¹

Data summary:

The 2019 Consensus Conference on SHK provided recommendations on eligibility criteria and safety net. The glomerular filtration rate (GFR) thresholds are based on analysis of heart recipients GFR and mortality rates.

Eligibility criteria

- Patients with established GFR < 30 ml/min/1.73 m² may be considered for SHK
- Patients with established GFR of 30–44 ml/min/1.73 m² and firm evidence of CKD such as small kidney size or persistent proteinuria >0.5 g/day in the presence of stable hemodynamics may also qualify for SHK on an individual basis

Safety Net

- Heart candidates with established GFR of 45–59 ml/min/1.73 m² may not be appropriate for SHK - they may benefit from a proposed safety net policy
- Heart recipients on chronic dialysis or with persistent GFR ≤ 20 ml/ min/1.73 m² for 6 weeks during day 30 to day 365 post-transplant should be given priority for kidney transplantation (donors with KDPI > 20%)

Summary of discussion:

The Chair inquired if additional steps had been taken since these discussions. The presenter informed the Committee that the group conducting the Consensus Conference had these discussions with the goal of the OPTN developing the policy that would follow and that the MOT Committee looked like the best place for that to occur.

A member noted the SHK data looked similar to that which preceded the development of SLK allocation policy and suggested mirroring the SLK policy for SHK. It was suggested to develop a common ground

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

threshold and safety net for multi-organ transplants and adjust as necessary when more data is collected. The presenter was in agreement with mirroring the policy for sustained acute kidney injury but was against increasing the GFR for chronic kidney disease (CKD) to 60 mL/min to align with SLK policy because it would qualify the vast majority of heart patients. A member encouraged the same policy for CKD heart patients because that despite the higher GFR they are still required to meet additional criteria to be eligible.

The presenter conceded that heart patients would have additional factors considered before being eligible, but was against the inclusion of dialysis as one an eligibility factor. Most heart failure patients are denied chronic dialysis because they do not have an exit strategy or are unable to physically handle the treatment in the first place. Members agreed that using the same 'one of the following' language would be acceptable for a SHK policy. A member suggested replacing 'small kidney size' with something more objective for consistency.

3. Lung-Kidney

Marie Budev, the Vice Chair of the OPTN Lung Transplantation Committee and member of the MOT Committee, presented literature on the Simultaneous Lung-Kidney Transplantation (SLuK).

Data summary:

Data on lung-kidney transplantation are more limited due to the smaller population of patients who have received these transplants. However, data shows lung candidates on dialysis prior to transplant gain a survival benefit from SLuK.

Summary of discussion:

The presenter added that the majority of lung kidney transplant are staged, not simultaneous. A member requested clarification on 'staged' and was informed that the transplant center identified living related donors pre-transplant for the kidney transplant.

A member inquired if the lung-kidney patients might be expected to recover kidney function after lung transplant, or if they are more similar to kidney-pancreas patients with established kidney disease. The presenter responded that there's always a small percentage that they could retain kidney function, however, the rate of immunosuppression is much higher for lung patients than any other solid organ transplant therefore compounding the injury to the kidneys. A member added that this explanation shows why a safety net for lung-kidney transplants is necessary. Despite the minimal data associated with this multi-organ combinations, utilizing the SLK policy as a roadmap will allow for developing a sound policy.

Due to the rate of immunosuppression needed for lung candidates, it seems more feasible for the SHK to mirror the SLK policy while the SLuK will likely require more organ-specific changes. Ultimately, the presenter shared the general view of lung transplant professionals is to allow lung recipients to recover for a year before determining if they should move forward with the kidney transplant.

4. Next Steps

UNOS staff outlined the goal to seek approval for a project on heart-kidney and lung-kidney eligibility criteria and safety net. UNOS staff asked if any additional information is needed to develop a proposal and how the Committee should proceed operationally.

Summary of discussion:

A member requested that the MOT Committee engage with the OPTN Kidney Transplantation Committee early on in this process. Other members echoed this sentiment encouraging engagement with the organ specific committees.

A member supported developing workgroups that pull in organ-specific experts to be the most efficient use of everyone's time, but added that the consensus conference has done the majority of the work for SHK so developing a policy should not be too time consuming especially if aligning it with SLK. Members agreed that the lack of data is a challenge for SLuK policy development and supported sharing it with the full Lung Committee to develop the education necessary to proceed in a workgroup with representatives from the Kidney Committee.

A member suggested engaging with the OPTN Data Advisory Committee (DAC) to see if there is information available on the lung waitlist form that would provide an estimate of how many patients would fall within the eligibility criteria and safety net.

A member suggested pursuing living donation from a family member when trying to determine between sequential and simultaneous organ transplant. The member added that living donation is promoted in pediatric transplant to reduce the burden on the deceased donor list and should be pursued in adult transplant as well. A member informed the Committee that this is often done for heart transplant patients but due to the age of the population there are extensive barriers to finding living donors. Another member supported including this language in the proposal to suggest exploring living donation first prior to utilizing the safety net.

Next Steps:

The Chair will work with UNOS staff to develop workgroups for moving forward with these policies proposals.

Upcoming Meeting

• July 26, 2021

Attendance

• Committee Members

- Alejandro Diez
 - o Charlie Alexander
 - Christopher Curran
 - o Dolamu Olaitan
 - o Evelyn Hsu
 - o Garrett Erdle
 - o James Pomposelli
 - o Jennifer Prinz
 - o Kurt Shutterly
 - o Marie Budev
 - Molly McCarthy
 - Nicole Turgeon
 - o Sandra Amaral
 - o Shelley Hall
 - o Vincent Casingal

• HRSA Representatives

- o Jim Bowman
- o Marilyn Levi
- o Raelene Skerda
- UNOS Staff
 - o Amber Wilk
 - o Eric Messick
 - o Kaitlin Swanner
 - o Laura Schmitt
 - o Leah Slife
 - o Matt Prentice
 - o Ross Walton
 - o Samantha Weiss
 - o Sara Rose Wells
 - o Sarah Konigsburg
 - o Susan Tlusty