OPTN Ad Hoc Multi-Organ Transplantation Committee Meeting Summary July 26, 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 07/26/2021 to discuss the following agenda items:

- 1. Review Data Advisory, Lung, Kidney, and Heart Committee Feedback
- 2. Project Goals
- 3. Multi-Organ Policy Review Workgroup Findings

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

1. Review Data Advisory, Lung, Kidney, and Heart Committee Feedback

UNOS staff shared the feedback from Data Advisory Committee (DAC) and Heart Committee while the MOT members who represent the Lung and Kidney Committees provided the feedback from their respective groups.

Data summary:

- The OPTN Data Advisory Committee endorsed the project and provided feedback on the current Simultaneous Liver-Kidney (SLK) criteria.
- The OPTN Lung Transplantation Committee supported using SLK criteria as a starting point and recommended extending the time frame for Simultaneous Lung-Kidney (SLuK) safety net.
- The OPTN Heart Transplantation Committee recommended using consensus conference thresholds for Simultaneous Heart Kidney (SHK) eligibility criteria and safety net.
- The OPTN Kidney Transplantation Committee supported a relatively strict eligibility criteria and supported the safety net for both SLuK and SHK.

Summary of discussion:

Data Advisory Committee Feedback

In response to DAC's suggestion to move away from creatinine-based estimates and use cystatin c to better estimate glomerular filtration rate (GFR), a member responded that they will often use both creatinine clearance and urea clearance to find a middle ground if the creatinine clearance over or under-estimates. Alternatively, the member suggested that each transplant center should be able to determine the approach for estimating GFR that best fits their patient. A member noted that no other allocation policy is as prescriptive, in terms of GFR, as the SLK policy is. The Chair suggested following the guidance from the Kidney Committee and what their best practice is.

A member shared that when developing the SLK policy they noticed a variation in the calculations that centers were using and wanted to provide a consistent standard to ensure accurate data collection. As this Committee moves forward the member urged them to try to be consistent with what's been done

before and that might mean needing to adjust the existing SLK policy. Other members echoed this sentiment, stating that now is the opportunity to revise and standardize the system.

A member informed the group that the Minority Affairs Committee developed a subgroup focused on GFR and shared that cystatin c was suggested when not using the coefficient for race but faced criticism as it may disadvantage some groups. The member suggested reaching out to the subgroup to assist with this discussion and promote consistent policy.

A member recommended that the OPTN select a standard approach for evaluating kidney function across liver-kidney, heart-kidney, and lung-kidney patients that allows programs to choose which calculation works best for their patients without cheating the system. A member noted the two issues in tension here – how to make a policy easiest to implement nationwide and how to make the policy more stringent to protect the kidney only candidates. This challenge existed when developing SLK policy and will persist through the MOT policy development. These policies are a give and take and the member suggested that either the test or the definition can be loose but not both.

Lung Committee Feedback

A member inquired as to why SLuK would need a safety net that is longer than 1 year. A member expressed concern about inviting controversy by extending the safety net for SLuK and therefore needing to consider extending it for other organs.

The presenter noted that while the Lung Committee made this point, they did not go into detail as to why they suggested this and the presenter will follow up with them. Safety net is a completely new concept for the Lung Committee and with more education and information, the presenter expected they will be able to come to a decision that is more consistent with the consensus of the rest of the organ committees.

Kidney Committee Feedback

A member noted that the SLK safety net has worked extremely well but sometimes results in 65 to 70year-old recipients receiving the organs of a 25 to 30-year-old donor and suggested revising the policy to reflect a more equal matching pattern, so that sequence B kidneys (those with a Kidney Donor Profile Index, or KDPI, between 20-34%) are allocated to younger candidates. A member responded that the best kidneys from sequences A and B (KDPI under 34%) tend to go to multi-organ candidates and that should not be the case every time. Alternatively, as the OPTN develops continuous distribution framework it would be possible to revise and develop more appropriate matching for candidates.

Members discussed the intent of those proposals juxtaposed with the potential outcomes. If the Committee develops a stricter eligibility criteria and safety net, then the proposals will likely reduce the number of multi-organ transplants and improve the access for kidney alone candidates. Continuing with this theme, members agreed that it may be better to adjust the sequence B eligibility now for all safety net candidates in order to gain greater support from the community. By making these changes now, it would hopefully gain the support of the kidney only candidates and alleviate the concern that they would have less access to high quality kidneys.

The member representing the Patient Affairs Committee shared support for stricter eligibility criteria in the hopes of few multi-organ transplants to not worsen the chances of a kidney alone patient.

Heart Committee Feedback

A member felt that it would be difficult to justify why the eligibility criteria thresholds for heart-kidney should be more lenient than for liver-kidney therefore inviting controversy into the MOT policies. A member added that liver and heart patients with renal disease can see improved kidney function after a

single organ transplant, though it is less likely for lung transplant patients. Another member added that the potential risk for Human Leukocyte Antigens (HLA) exposure has been greatly reduced and should be viewed as a theoretical risk instead of a strong argument in favor of simultaneous transplantation. A member encouraged keeping a consistent policy for multi-organ transplants that would be easier for patients to understand.

General Feedback

The Chair noted that at some point, the MOT Committee should provide clarity on how an Organ Procurement Organization (OPO) should start to allocate organs from a multi-organ donor. The representative from the OPO Committee is planning to share to the work done by that group in discussing when to prioritize a certain MOT combination over another or a single-organ transplant. The Chair identified that the ultimate goal of this group would be to develop a consensus and unified approach to best serve the patients on the waiting list.

2. Project Goals

The Chair lead the discussion about the project goals.

Summary of discussion:

A member noted the necessity to balance risks when predicting the success of a transplant with likelihood of patient survival and organ waste. This member's transplant center discussed the idea of doing renal scans at 6 and 12 month follow ups for SLK patients to determine if the kidneys regained function after transplant. The Chair encouraged the Committee to identify areas for increased data collection to continue to improve the policy and make data driven decisions. A member added that it'll be essential to develop guidance for the OPOs to explain to the kidney alone community how these transplants will be limited.

The Patient Affairs Committee representative encouraged the Committee to make a decision that had a clear and simple answer so the patient community can understand when and why a multi-organ transplant may take precedent over a single-organ transplant. The patient representatives were in favor of developing a framework that is consistent across all multi-organ combinations to provide a greater sense of clarity to the patient, especially when there is so little predictability as to when a multi-organ transplantation could occur.

A member shared that when developing SLK policy there was a lot of unknowns that were unable to be answered until a policy was developed and specific data was gathered. While these tough decisions are going to continue to occur in this policy development process, it's essential to think globally and know it can be adjusted down the line.

A member added that MOT should not always come first on the match run and that can be done through limiting the eligibility criteria. There needs to be a balance between multi-organ and singleorgan transplant. A member emphasized the importance of determining, at some point, who comes first in the match run, whether that is pediatric candidates, highly sensitized candidates, or other medically urgent candidates.

A member echoed this sentiment and added that if the secondary on the liver match run is an SLK candidate then the OPO is left holding the kidney as a backup if the liver alone candidate declines. This can create an issue of every organ being a back up to every other organ. This issue resonated strongly with another member who encouraged that back up organs should be released two hours prior to procurement.

A member proposed the possibility of never doing simultaneous transplants and always utilizing the safety net for kidney combinations to see if kidney function recovers following transplant. A member responded this idea had been considered when developing SLK policy but ultimately the data showed that SLK transplants had better outcomes than kidney after liver transplants. A member highlighted the difference between livers and thoracic organs, particularly the increased difficulty of perioperative management for thoracic patients, and urged the Committee to stay away from comparing every multiorgan combination to livers.

Next steps:

UNOS staff will send invitations for the next meetings and move forward with developing a consensus on eligibility criteria.

3. Multi-Organ Policy Review Workgroup Findings

Due to time constraints, the Committee Chair reserved this discussion for a future meeting to allow for sufficient time for discussion.

Upcoming Meetings

- August 16, 2021
- August 30, 2021
- September 20, 2021
- October 12, 2021
- November 1, 2021
- November 22, 2021

Attendance

• Committee Members

- o Alden Doyle
- Charles Alexander
- o Chris Curran
- o Garrett Erdle
- o James Sharrock
- o Keren Ladin
- o Kurt Shutterly
- o Marie Budev
- o Nicole Benjamin
- o Nicole Turgeon
- o Oyedolamu Olaitan
- o Shelley Hall
- o Vincent Casingal
- HRSA Representatives
 - o Jim Bowman
 - o Marilyn Levi
- SRTR Staff

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- o Jon Snyder
- Katie Audette
- UNOS Staff
 - o Amber Wilk
 - o Holly Sobczak
 - o Kaitlin Swanner
 - o Laura Schmitt
 - o Leah Slife
 - Matt Prentice
 - o Ross Walton

• Other Attendees

o Jon Miller