

Meeting Summary

OPTN Ad Hoc Multi-Organ Transplantation Committee Meeting Summary January 11, 2023 Conference Call

Lisa Stocks, RN, MSN, FNP, Committee Chair

Introduction

The ad hoc Multi-Organ Transplantation Committee met via Citrix GoToMeeting teleconference on 01/11/2023 to discuss the following agenda items:

- 1. Review Regional Meeting Presentations
- 2. Update on Heart-Kidney and Lung-Kidney Implementation
- 3. Kidney MOT Project: Policy Language Review

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

1. Review Regional Meeting Presentations

The Committee Chair reviewed the regional meeting presentations, schedule, and expectations for members presenting at their upcoming regional meetings.

Identify Priority Shares in Kidney Multi-Organ Allocation Discussion

The Policy Oversight Committee (POC) Chair brought up that the Executive Committee had discussed how the KDPI of kidneys being offered would affect the decisions of how a kidney would be shared. She mentioned that this concept paper is a first step, and after the values of the community are clearer that is something to address. OPTN Contractor staff mentioned that some information on KDPI is mentioned in the concept paper, considering limiting KDPIs by sequence for pediatric and adult kidney alone candidates. She requested the thoughts of the committee on how to further shape the conversation around the topic or whether to avoid it at this stage of the concept paper. The Multi-Organ Transplantation (MOT) Chair agreed that these are good concerns to bring up, but that this is a first high-level attempt at the conversation for multi-organ versus single-organ kidney allocation, and that whoever is presenting should say in the beginning that the committee is seeking feedback that will then be incorporated. The POC Chair agreed and stated that it's important feedback but that isn't where the project is right now. Another member mentioned that they could introduce the concept of donor-recipient longevity matching as a way to introduce the concept without going too far into the weeds. The MOT Chair agreed and said that if it's in the concept paper it may be something for OPTN Contractor staff to incorporate in the slides.

Another member mentioned that it would be helpful to have data on the volume of kidney multi-organ transplantation in the extra slides for the proposal, in order to ensure the discussion doesn't get off track and is grounded in data.

Expand Required Simultaneous Liver-Kidney Allocation Discussion

One member asked for clarification, if a simultaneous liver-kidney (SLK) candidate is beyond 500 nautical miles (NM) from the transplant hospital, if the kidney could be allocated to the SLK candidate or if it would be mandated to be allocated to a kidney alone candidate. OPTN Contractor staff clarified that current policy states that after required SLK shares, OPOs are able to offer kidneys to single organ

transplant recipients or MOT recipients. An OPO representative on the committee stated that while there should be flexibility in allocation, he was concerned that the same scenario of differences in OPO practices causing unequal allocation practices across the country would occur again. The MOT Chair stated that it will likely be a topic of discussion in some regional meetings, but that it's important to remind members that we will monitor the policy. She stated that the goal is to attack the disparity we see now, and if more disparities arise later, we will address them then.

One member asked which match run an OPO needed to start with first, and if the question to the community on whether after completing required SLK shares the OPO should be required to offer the kidney to kidney-alone candidates and liver to liver-alone candidates restricted offers to heart-liver candidates. The Chair clarified that the intent was to lessen the restrictions that currently exist in policy. The member then asked if SLK allocation was required to come before multivisceral allocation. Another member stated that the current allocation policies prioritize multivisceral transplantation for donors less than 18 years old, and SLK transplantation for donors greater than 18 years old. The MOT Chair then clarified that policies set the order of the allocation, but that the OPO allocating organs will go straight down the match run. Another member stated that SLK allocation will likely be primarily driven by the liver allocation, just in the way it's operationalized.

2. Update on Heart-Kidney and Lung-Kidney Implementation

The OPTN Contractor's Information Technology (IT) Service Owner presented implementation plans for *Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation*.

Data summary:

The IT Service Owner reviewed the following information:

- Slated for implementation Summer 2023
 - Phased implementation will allow transplant programs to start entering data regarding eligibility criteria and safety net prior to implementation so that candidates can start receiving offers accordingly when policy is implemented
- Safety net eligibility will be retroactive
 - If transplant program can provide data showing that a kidney candidate met the safety net criteria between 60-365 days following a heart or lung transplant, they will get the safety net priority
 - This applies even if the heart or lung transplant occurred over 365 days ago

The IT Service Owner then reviewed the policy language and gave an example of an eligible candidate under the safety net.

The IT Service Owner then reviewed that with the 2023 implementation, the OPO will be required to offer both the kidney <u>and</u> the liver to candidates who meet the criteria for both organs, rather than just offer the kidney or the liver to those candidates.

The IT Service Owner showed the committee a form available in the OPTN Waiting List to assist transplant programs in documenting candidate eligibility for SLK offers and asked if transplant programs are using the form and if it should be replicated for heart-kidney and lung-kidney candidates. She also asked if members had any suggestions for communicating pending changes to transplant programs.

Summary of discussion:

One member asked if the safety net would be applied retroactively, for example to a lung candidate who met this criteria four years ago and is still waiting for a kidney. OPTN Contractor staff clarified that this would apply retroactively, similarly to how the SLK policy was originally rolled out.

One member asked if the waiting time modifications for race-based eGFR would apply to safety net candidates for heart and lung. OPTN Contractor staff stated that we never specified what calculation must be used for the eGFR calculation for safety net candidates, so if the transplant hospital can demonstrate that the candidate would have met the qualifying criteria using a race-neutral formula it would likely be acceptable. Another member stated that based on the current policy requiring a race-neutral formula, transplant hospitals would likely be required to enter the race-neutral eGFR values. The original member mentioned that this was a point of discussion at the Board meeting, how far back transplant programs would be required to go for race-neutral calculations, and that this would be a wider net to increase equity for candidates. The other member agreed and stated that based on current policy it seems like members would need to use a race-neutral calculation for the safety net candidates.

One member asked what the start date is used for waiting time for safety net candidates. OPTN Contractor staff clarified that it would be the earliest qualifying time for safety net. Another member stated that the first qualifying eGFR gives you 30 days of safety net, then you have 90 days of qualifying values at which point the safety net is permanent. The original member asked if there are multiple organs being allocated to safety net recipients, if they are ranked by waiting time. The other member stated that in their experience, it's been a very short waiting time, between one and three months and that the waiting time isn't too impactful because the transplant is faster than expected.

One member asked for clarification of the candidate qualifying criteria needing to occur within 60-365 days of transplant. OPTN Contractor staff clarified that the candidate would have to have been registered for a kidney within 365 days of the initial heart or lung transplant. Another member clarified that the idea of the 60 days at the beginning timeframe was for acute kidney injuries to improve, and 365 was so that the transplant wasn't causing chronic kidney injury and being transplanted under a safety net.

Another member asked if when the original SLK implementation occurred, it looked at candidates retrospectively to see if they were active and eligible within the safety net timeframe, in order to be consistent. The MOT Chair and OPTN Contractor staff stated that it was the case.

One member asked if a patient needed to be registered within 365 days, or needed to qualify within 365 days, as it could be impacted by the race-neutral eGFR issue. OPTN Contractor staff clarified that they would need to both register and qualify within that time period. Another member asked if the waiting time modification for eGFR would impact this eligibility for registration, if there would be additional flexibility. OPTN Contractor staff stated they would clarify the point and bring the answer back to the committee.

One member asked if moving forward the Committee would need to consider the KDPI of the organs offered through safety net, and if it is appropriate to allocate low KDPI kidneys that way. Another member clarified that sequence A kidneys aren't allocated to safety net, only B, C, and D, and that heart and lung policy was modeled to mirror liver policy. Another member agreed, and stated that the Committee could evaluate whether it is appropriate to offer sequence B kidneys through safety net as well.

One member asked when the patient's waiting time starts, when they receive their first organ transplant or when they register for the kidney. OPTN Contractor staff clarified that the waiting time starts at the date of first qualifying test or treatment, and that kidney allocation will still be managed under kidney

allocation policies. Staff also stated that this will be in the FAQ as well. A member asked if the SLK FAQ could be sent to the Committee as well. Another member asked if the FAQ would be able to have real-life examples, and stated that it helps members understand it better. Staff stated that they could work on it for implementation.

Multiple members agreed that if there was an eligibility worksheet for liver-kidney, there should be one for heart-kidney and lung-kidney. One member asked if there could be a direct link to an automated program for members to calculate eGFR. OPTN Contractor staff will follow-up.

One member asked why there aren't eligibility criteria worksheets for other multi-organ combinations, and another clarified that there weren't eligibility criteria for any other MOT combinations before, only livers.

Members asked if the implementation educational materials could include all of the same materials from SLK. Another member asked if there could be a webinar, possibly showing how to fill out data forms and with a live question and answer session. The member recommended the webinar be prior to implementation. Other members agreed a webinar would be helpful.

3. Kidney MOT Project: Policy Language Review

The Committee Chair reviewed policy language related to kidney MOT allocation with the committee for feedback for work on the project to identify priority shares in kidney multi-organ allocation.

Summary of discussion:

Multiple members stated that OPTN *Policy 8.7.A: Choice of Right versus Left Donor Kidney* is hard on host OPOs allocating to MOT candidates.

Multiple members stated that it would be helpful to combine all kidney MOT policies into one section.

One member brought up that the committee needs to consider directed donation in the project, since if there is a directed recipient there will only be one other kidney available. Another member agreed, and stated that OPOs have to prioritize directed donation under federal law. The original member brought up that in practice the directed donor is able to choose laterality of the kidney. The other member stated that they think of it as the directed donor is the highest priority class for choice, which should be specified in policy. Another member stated that the priority for laterality should be first the directed donor, and then the candidate highest on the kidney waiting list.

One member asked if anybody knew the background on paragraph 2 of OPTN *Policy 8.7.A: Choice of Right versus Left Donor Kidney* and stated that it seemed confusing. OPTN Contractor staff will bring information to an upcoming meeting. The member stated that the first paragraph seemed to cover the relevant information, but they weren't sure if that portion of policy was added to solve another problem they hadn't considered.

Next steps:

Members will review the kidney MOT policies prior to the next meeting and then speak to their recommendations.

Upcoming Meetings

February 8, 2023, 3:00 PM ET

- March 8, 2023, 3:00 PM ET
- April 12, 2023, 3:00 PM ET

Attendance

• Committee Members

- o Alden Doyle
- o Chris Curran
- o Dolamu Olaitan
- Heather Miller-Webb
- o Jim Sharrock
- o Kenny Laferriere
- o Lisa Stocks
- o Marie Budev
- o Nicole Turgeon
- o Rachel Engen
- o Sandra Amaral
- o Valerie Chipman
- o Vince Casingal

• HRSA Representatives

- o Jim Bowman
- o Marilyn Levi

SRTR Staff

- o Jon Snyder
- o Katherine Audette

UNOS Staff

- o Alex Carmack
- o Courtney Jett
- o Julia Foutz
- o Kaitlin Swanner
- o Matt Cafarella
- o Paul Franklin
- o Sara Langham
- o Susan Tlusty