

Meeting Summary

OPTN Ad Hoc Multi Organ Transplantation Committee
Simultaneous Liver-Kidney Workgroup
Meeting Summary
September 27, 2022
Conference Call

Lisa Stocks, RN, MSN, FNP, Chair

Introduction

The Simultaneous Liver-Kidney Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 09/27/2022 to discuss the following agenda items:

- 1. Welcome and Agenda
- 2. Project Background, Scope, and Timeline
- 3. Data Request

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

1. Welcome and Agenda

The Chair welcomed the Workgroup and introduced the agenda for the meeting. The Chair also introduced the Workgroup members to one another.

2. Project Background, Scope, and Timeline

This project is to align required shares for simultaneous liver-kidney (SLK) allocation with required shares for heart-kidney and heart-liver allocation and is currently in the evidence gathering stage. The Workgroup is responsible for submitting a data request and considering changes to SLK policy relating to distance and the Model for End-Stage Liver Disease (MELD)/Pediatric End-Stage Liver Disease (PELD) thresholds. The Multi-Organ Transplantation Committee is the sponsor for the project and all recommendations from the Workgroup will go to the MOT Committee for further discussion and voting. The Workgroup will aim to deliver their recommendations in time for the MOT Committee to send the proposal out for public comment in January 2023.

Summary of discussion:

The Workgroup discussed whether there is variation in donor availability within 250 nautical miles (NM) versus 250-500 NM for SLK depending on location, and whether expanding required shares for SLK would impact other kidney multi-organ and kidney-alone candidates. The Chair asked if there are other approaches to addressing the concerns identified by the Liver & Intestine Committee regarding unequal access to SLK transplantation across the country.

A member explained that the 250 nm circle around his center is actually smaller than the donation service area (DSA) prior to the allocation change that eliminated DSAs as a unit of allocation. The member does not think that access to SLK transplant is an issue everywhere across the country. However, the member noted that there is variation in whether organ procurement organizations (OPOs) are willing to share the kidney along with the liver to candidates who fall outside the geographic threshold for required shares but meet the medical eligibility criteria. The member said that providing the kidney along with the liver helps to ensure better post-transplant outcomes. The member acknowledged concerns about pulling kidneys unnecessarily and patients walking around with three

functioning kidneys because they received a kidney transplant that they did not really need. The member believes that the SLK medical eligibility criteria addresses that issue. The member acknowledged that the kidney-after-liver safety net allows people who don't qualify for required SLK shares to get kidney later, but the member has heard that some patients may not be able to access the safety net because they are too sick. The member said that the liver-kidney policy should be aligned with the heart-kidney policy, and that this is a fairness issue that should not be up to the discretion of an OPO.

Another member asked if, for regions that have fewer OPOs, expanding the required share range to 500 NM would help. A member replied that it would make a difference for a few liver-kidney patients, where the liver was outside of the 250 NM circle, and the OPO would not provide the kidney. A member said that it would be reasonable to align the kidney MOT policies to extend out to 500 nm.

The Chair asked if the Workgroup should also reconsider the MELD thresholds and whether it makes sense to have a MELD restriction. Members noted that generally transplant programs and OPOs have supported sending organs farther for patients who are sicker. Staff noted that the OPTN white paper *Ethical Implications of Multi-Organ Transplants*¹ recommended prioritizing candidates for multi-organ transplant if they have medical urgency for both organs but not if they only have medical urgency in one organ, and that the current MELD/PELD thresholds for SLK aligns with the classifications in liver allocation. A member noted that the MELD threshold of 29 is an inflection point at which medical urgency escalates.

3. Data Request

The Workgroup discussed submitting a data request to inform their project work. The primary questions the Workgroup wants to answer are:

- Is there variation in donor availability within 250 nm vs. 250-500 nm for SLK depending on location?
- How will expanding circle sizes for SLK impact kidney-alone/kidney-pancreas/heart-kidney/lung-kidney candidates?

Summary of discussion:

The Workgroup reviewed possible analyses:

- Number of candidates listed for SLK and the proportion of those that receive SLK transplant over time
 - Gives a sense of the overall volume of SLK candidates waiting and SLK transplants performed
 - Examine SHK candidates/transplants for comparison
- Number of SLK candidates waiting and the number of SLK transplants performed within 250 NM vs. 250-500 NM from each donor hospital
 - Number of candidates in the 250-500 NM circle would represent the maximum number (upper bound) of additional candidates who could potentially pull a kidney from a kidney-alone candidate if SLK required shares are increased to 500 NM

The Workgroup discussed which cohort dates are of interest for counting candidates waiting, and which dates are of interest for counting transplants. The Workgroup agreed to:

¹ "Ethical Implications of Multi-Organ Transplants," OPTN, White Paper, accessed October 25, 2022, https://optn.transplant.hrsa.gov/media/2989/ethics_boardreport_201906.pdf.

- Use snapshot data for counting candidates waiting, which captures all candidates waiting on the last day of each month, including only waitlist registrations occurring post-acuity circles implementation (Feb. 2020 or later)
- The Workgroup agreed to only include transplants occurring post-acuity circles implementation

A member suggested looking at incidents when an OPO has shared the kidney with the liver outside of the policy requirements, to get a better understanding of any increase in SLK that might occur due to new policy language. One member acknowledged the potential benefit of a policy change for the less populated western portion of the country and asked whether there is a chance for unintended consequences in more densely populated areas. Another member replied that expanding required shares to 500 NM would probably not cause many issues in the densely populated areas. The Chair suggested that if a policy change would only impact a small number of candidates in certain regions, then maybe a policy change is not needed. A member said that just because it is a small population does not mean that the policy should not be changed if it is disadvantaging candidates. A member expressed concern about the increase in travel and costs, asking whether having differential policies based on area density might be preferable.

Staff presented OPTN data showing that over 25 percent of SLK transplants occur between 250-500 NM, where sharing the kidney with the liver is permissible but not required by policy. Members discussed clarifying this language in policy. A member expressed concern that expanding the range outside of 250 NM would disadvantage kidney-alone candidates, particularly highly sensitized and pediatric kidney candidates, since organs that go towards multi-organ transplants tend to be of higher quality. The member said that the workgroup must also consider the potential impact on simultaneous pancreas-kidney allocation and whether pancreas allocation should also be expanded out to 500 NM. The member said that the Workgroup has to figure out how to gauge medical urgency for multi-organ candidates relative to access to transplant for kidney candidates. A member replied that patients who receive a liver-alone transplant instead of SLK are having poor outcomes and are too sick to get a kidney later.

Members deliberated changing the language in the eligibility criteria to say if a patient meets the criteria, they will be offered a kidney with the liver, regardless of the geographic distance or MELD/PELD threshold. Some felt that incremental change would be a better initial step, and that a proposed change would get more support from the kidney community if there are bounds on required SLK shares. The member noted that the heart-kidney policy did include some restrictions on heart medical urgency status to place some restrictions on required shares. A member supported maintaining guardrails in the policy to protect access to transplant for kidney-alone candidates, as they make up the largest portion of the waiting list and typically wait the longest. The member mentioned that most multi-organ transplants involve a kidney and each of those transplants means one less kidney for someone on the waiting list.

The Workgroup agreed to move forward with a data request. A member asked if there is a way to see the Kidney Donor Profile Index (KDPI) of the kidneys allocated as SLK, and to include that in the data request. Research staff agreed to include that and added that they could map out results onto the regions to provide insight into whether this problem affects certain regions more than others.

Next steps:

The Workgroup will reconvene in 4-6 weeks when the results of the data request are available.

Upcoming Meeting

TBD

Attendance

• Workgroup Members

- o Lisa Stocks
- o Alden Doyle
- o Christopher Curran
- o Donna Smith
- o Jim Kim
- o Jim Sharrock
- o Peter Abt
- o James Pomposelli
- o Rachel Engen
- o Sandra Amaral
- Stephen Almond

• HRSA Representatives

o Jim Bowman

SRTR Staff

- o Katherine Audette
- o Jon Snyder
- Jonathan Miller

UNOS Staff

- o Erin Schnellinger
- o Holly Sobczak
- o Julia Foutz
- o Kaitlin Swanner
- o Krissy Laurie
- o Lindsey Larkin
- o Matt Belton
- o Matt Cafarella
- o Meghan McDermott
- o Melissa Lane
- o Susan Tlusty
- o Sara Langham
- o Ben Wolford