

OPTN Ad Hoc Multi-Organ Transplantation Committee

Meeting Summary

October 12, 2022

Conference Call

Lisa Stocks, RN, MSN, FNP, Chair

Introduction

The Ad Hoc Multi-Organ Transplantation (MOT) Committee met via Citrix GoToMeeting teleconference on 10/12/2022 to discuss the following agenda items:

1. Simultaneous Liver-Kidney and Continuous Distribution Project Updates
2. Clarify Multi-Organ Allocation Policy: 6-Month Monitoring Report
3. New Project: *Identify Priority Shares in Kidney Multi-Organ Policies*

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

1. Simultaneous Liver-Kidney and Continuous Distribution Project Updates

The Committee received an update on the progress of the Simultaneous Liver-Kidney (SLK) Workgroup and the Continuous Distribution of Kidneys and Pancreata project.

Project updates:

SLK Workgroup:

- Held first meeting on September 27, 2022
- Submitted a data request
- Will reconvene once data is available for review

Continuous Distribution of Kidneys and Pancreata

- Kidney and Pancreas Transplantation Committees will review the results of the first round of modeling this month
- The Committee will review and provide feedback on the modeling results in November

Summary of discussion:

The Committee had no questions or comments.

2. Clarify Multi-Organ Allocation Policy: 6-Month Monitoring Report

The Committee reviewed the results of the 6-month post-implementation monitoring report for the *Clarify Multi-Organ Allocation* policy update.

Data summary:

The *Clarify Multi-Organ Allocation* policy update, initially proposed by the Organ Procurement Organization (OPO) Committee, updated OPTN Policy 5.10.C: *Other Multi-Organ Combinations*:

- Established requirements for sharing a kidney or a liver with a thoracic organ
 - Specified kidney and liver as "second organ"

- Heart, Lung, and Heart-Lung are considered the primary organs which pull the secondary organ in a multiple organ offer/transplant

OPTN Policy 5.10.C: *Other Multiple Organ Combinations* establishes the following shares as required:

- Heart-Kidney or Heart-Liver
 - Within 500 nautical miles (NM)
 - Adult Status 1, 2, or 3
 - Pediatric Status 1A and 1B
- Lung-Kidney or Lung-Liver
 - Within 500 NM
 - Lung allocation score (LAS) greater than 35
 - Lung candidates younger than 12 years old
- Heart-Lung-Kidney or Heart-Lung-Liver
 - Within 500 NM
 - Adult Heart Status 1, 2, or 3
 - Pediatric Heart Status 1A or 1B
 - LAS greater than 35
 - Lung candidates younger than 12 years old

This analysis includes metrics regarding multiple organ transplants and OPTN waiting list additions and removals stratified by share type (transplants), medical urgency by organ, age group, and distance (transplants). Due to small numbers, only select metrics could be broken out by multi-organ combination. Metrics were compared across the following eras:

- Pre-policy: October 12, 2021 – February 9, 2022
- Post-policy: February 10, 2022 – June 10, 2022

Multi-organ thoracic transplants – deceased donor transplants where a heart, lung, or heart-lung were transplanted with a kidney, liver, or kidney and liver from the same donor into a single candidate

- There was an increase in multi-organ thoracic transplants from the pre-policy era, with 6.3 percent (123) thoracic transplants to 8.4 (193) percent of thoracic transplants post-policy
- Heart multi-organ transplants increased from 9.43 percent to 13.29 percent of heart transplants
- Lung multi-organ transplants increased from 0.93 percent to 1.4 percent of lung transplants
- Heart-lung increased from no multi-organ transplants at 0 percent to 2 multi-organ transplants (9.09 percent of all heart-lung transplants)
- In all eras for the Heart, Lung, and Heart-Lung the majority of multiple organ transplants were required shares
 - The number and proportion of permissible shares increased for heart and lung multi-organ transplants
- The proportion and number of lung or heart-lung transplants where the recipient LAS was less than 50 increased in the post-policy era
 - Median LAS for multi-organ recipients decreased from 58 in the pre-policy era to 40.26 in the post-policy era
- Proportion and number of multi-organ heart or heart-lung transplants where the recipient was Status 3 or Status 5 increased considerably in the post-policy era
- The proportion and number of multi-organ transplants where the recipient had a median end-stage liver disease (MELD) or pediatric end-stage liver disease (PELD) score of 15 to 19 increased considerably in the post-policy era

- Slight increase in those with a MELD/PELD of 25 or greater at transplant
- No recipients of a multi-organ transplant containing any combination of a heart or lung with a kidney was medically urgent at time of transplant for kidney
 - 3 recipients were inactive for a kidney at time of transplant in the post-policy era
- All pediatric multiple organ thoracic transplants were heart-liver or heart-kidney, and transplant counts remained consistent with four in the pre-policy timeframe and four in the post-policy timeframe
- For heart-kidney and lung-kidney, there was an increase in the number of transplants occurring outside of 500 NM from the donor hospital in the post-policy era

OPTN multiple organ thoracic waiting list additions – registrations for a heart, lung, or heart lung where the candidate was additionally listed for a kidney, liver, or both a kidney and liver at time of listing

- There was an increase in heart multi-organ registrations from 184 to 234 listings in the post-policy era
 - Multi-organ listings for lung remained similar across eras
- Proportion and number of multi-organ lung and heart-lung registrations where the candidate's LAS at listing was 40 or greater decreased in the post-policy era
 - Pre-policy – 54.55 percent; post-policy 47.06 percent
- Proportion of multi-organ heart and heart-lung registrations remain consistent across all statuses, with a slight jump in registrations for adults status 5
- Number of heart-liver and lung-liver candidates with a MELD/PELD of less than 25 increased
- No thoracic multiple organ candidate containing any combination of heart or lung with a kidney qualified for kidney medically urgent status at time of listing
- Pediatric listings for multi-organs increased from 4 listings to 10 listings, and all were either heart-liver or heart-kidney

OPTN multiple organ thoracic waiting list removals includes candidates listed for a heart, lung, or heart-lung as well as a kidney, liver, or both kidney and liver at time of removal. If a candidate had multiple registrations, their removal is counted once in accordance to the earliest removal date reported for the candidate.

- Removal due to death or “too sick” decreased for heart multiple organ candidates from the post-policy era to the pre-policy era, while removals due to death or “too sick” remained consistent for lung
- As many heart candidates are listed as inactive before being removed due to death or too sick between the pre-policy and post-policy era
 - Pre-policy – 79.49 percent (31); post-policy 65.62 percent (21)
- There was an increase in removals due to death or too sick for candidates whose last known active status was adult heart status 2
 - Pre-policy – 20.51 percent (8); post-policy – 40.63 percent (13)
- There was also a considerable decrease in removals due to death or too sick for candidates whose last known active status was adult heart status 4
 - Pre-policy 28.21 percent (11); post-policy – 15.62 percent (5)
- The LAS at removal for multi-organ lung and heart-lung candidates removed due to death or too sick was greater than 50 for all six candidates (two in the pre-policy, and four in the post-policy)
- Only one pediatric multi-organ candidate was removed due to death or too sick across the monitoring time frame, and it occurred in the post-policy era

- As many heart-liver, lung-liver, and heart-lung-liver candidates are listed as inactive before being removed due to death or too sick
 - The majority of candidates removed for death or too sick had a MELD/PELD at removal or last known MELD/PELD of less than 20

Conclusion:

- Increase in multiple organ transplants containing a heart and/or lung in part driven by an increase in permissible shares
 - Decrease in median LAS at transplant
 - Increase in heart status 4/5 at transplant
- Transplant was the main reason for candidate removal from waiting list for multiple organ thoracic candidates
 - Removals due to death or too sick decreased for heart and remained consistent for lung
- Small numbers make it difficult to determine the true impact of this policy. Further analysis and data are needed.

Summary of discussion:

The Chair remarked that this monitoring report shows that the effects of the *Clarify Multi-Organ Allocation Policy* update are still somewhat inconclusive, and expressed surprise that the majority of changes were around permissible shares.

One member pointed out that when the thoracic allocation system prioritizes sicker hearts and livers, because heart and liver dysfunction lead to kidney dysfunction, the recipients of mandatory multi-organ offers will also be sicker. The member continued that there is a natural split with the LAS score because lung processes don't drive kidney disease. The member noted that this is predictable based on the biology of disease. The member noted that, for liver candidates with poor kidney function, the poor kidney function and dialysis alone typically lead to reasonably high MELD scores of around 20. The member expressed curiosity about the increase in transplants for recipients with a MELD/PELD of 15 to 19.

A member pointed out that many heart-liver patients have compensated cirrhosis, and that the necessity for transplant for many of those patients is driven by heart failure. The member noted that the heart transplant recipient with cirrhosis may not be able to survive the heart transplant without a liver transplant as well, and this explains the low MELD/PELD score for simultaneous heart-liver recipients. The member added that there will be a growth in heart-liver transplants due to the large population of young adults that have successfully navigated 20 or 30 years since their Fontan procedures who are now developing cirrhosis and heart failure. The member noted that these patients will require combined transplants in the next few years.

One member noted that the increase in permissible shares may be a result of COVID-19-era data, where transplant program and OPO behavior varied significantly. Staff shared that the OPTN OPO Committee was also unsure what was driving the increase in permissible shares.

One member asked if the report included the kidney donor profile index (KDPI) of the required shares, similar to how the thoracic-liver transplants were broken out by MELD and PELD. The member noted that it is easier to get a kidney placed when it's part of a liver-kidney transplant. Another member noted that this data related to heart-livers and lung-livers. The member that most extra-renal transplants involve low KDPI kidneys, as these transplants don't recover well with high KDPI kidneys.

A member agreed that many of these thoracic multi-organ patients with low MELD scores are low MELDs because their heart could not survive a high MELD. The member explained that, for heart-liver

patients, cirrhosis patients can't receive a heart alone without a liver transplant, or else the heart fails. The member explained that the heart needs to drive the patient's access to transplant, as these candidate's heart cannot survive a high MELD.

The Chair noted that these are very sick heart patients, but the liver is not as sick as the heart. A member pointed out that these patients do have sick livers, as they do have cirrhosis. The member responded that there currently is no standard, but the American Society for Transplantation (AST) just completed a consensus conference on recommendations for the heart-liver. The member shared that the only absolute consensus was on biopsy-proven cirrhosis patients needing both a heart and a liver. The member shared that the more nuanced factors, such as advanced fibrosis or stage 3 fibrosis with high venous pressure is still under debate. The member concluded that the only thing agreed upon for heart-liver was biopsy proven cirrhosis.

A member pointed out that some of the permissible shares were beyond 500 NM, noting that heart and lungs typically can't tolerate extended cold ischemic time. The member continued that new perfusion technology will allow these organs to travel further and tolerate more cold ischemic time, and so these organs may be traveling further in the future. Another member agreed, adding that this is true even with donation after circulatory death (DCD) donors, particularly with the Organ Care System (OCS) perfusion for the heart.

Staff shared that the OPTN 2019 White Paper on Multi-Organ Transplant¹ recommended that generally, allocation should prioritize candidates who have medical urgency in both organs, unless there is other clinical justifications. Staff noted that this monitoring report shows that, with the heart-liver transplant and heart-kidney transplant, there is a balance in terms of the candidates that are too sick or medically urgent in one organ, then the transplant can't be performed. The Chair agreed. Another member noted that the white paper didn't fully take into account the practicality of performing multi-organ transplants. The member continued that when two deceased donor organs are transplanted, the second organ must allow the first organ to survive the perioperative period, making an abdominal-thoracic combination a difficult transplant to perform successfully. The Chair remarked that the Committee could further discuss the definition of organ failure to determine how that should factor in to decision making going forward.

3. New Project: *Identify Priority Shares in Kidney Multi-Organ Policies*

The Committee continued discussions on their current project, *Identify Priority Shares in Kidney Multi-Organ Policies*.

Presentation summary:

Project timeline:

- October 17 – Policy Oversight Committee (POC) review
- October 26 – Executive Committee review
- November 9 – Finalize concept paper
- January 2023 – Release concept paper for public comment
- August 2023 – Submit policy proposal for public comment

Today's discussion will include identifying concepts to be included in the concept paper and questions to ask the community during public comment.

¹ "Ethical Implications of Multi-Organ Transplants," OPTN, White Paper, accessed November 9, 2022, https://optn.transplant.hrsa.gov/media/2989/ethics_boardreport_201906.pdf.

Kidney required shares include two main populations of concern:

- Candidates who are hard to match and may not get another offer (high Calculated Panel Reactive Antibody, or CPRA)
- Candidates who are medically urgent or warrant priority for low KDPI kidneys (pediatric, pancreas-kidney)

Previously, the Committee discussed that it may be appropriate to develop different allocation approaches for these populations

Kidney medically urgent patients must qualify per OPTN Policy 8.5.A.i: *Medically Urgent Status for Adult and Pediatric Candidates*. From March 15th, 2021 to August 1, 2022, there were 29 candidates listed with a medically urgent status, 14 of which were transplanted and 3 of which were removed from the waitlist due to death. Median time waited at medically urgent was 59 days, and maximum was 501. There was a bolus of new medically urgent cases following implementation but the rate has leveled out to about one new case per month.

Questions for discussion:

- Should only high CPRA kidney candidates be given kidney offers prior to kidney MOT candidates?
- Should kidney MOT candidates have priority over medically urgent kidney alone candidates?
- Should pediatric kidney-alone candidates get additional priority for low KDPI kidneys relative to kidney MOT candidates?
- What other questions should we ask in public comment related to required kidney offers?
- Previously, the Committee discussed that this project should address laterality
 - How do OPOs currently determine when to offer the right or left kidney?
 - What policy might you propose to assist OPOs with this?

Other topics for the concept paper:

- Determining priority among multi-organ kidney candidates (heart-kidney, lung-kidney, liver-kidney, and pancreas-kidney)
- Clarifying policy when OPOs have required multi-organ shares but organs have been accepted elsewhere

Summary of discussion:

One member noted that the other 12 candidates who were listed at medically urgent but were not transplanted or removed from the waiting list may be still waiting, potentially as a result of being highly sensitized.

The Chair shared a list of recommendations for consideration from the OPTN Pediatric Transplantation Committee, including:

- Discussion regarding which pediatric patients should have higher priority
 - CPRA in pediatrics should be a priority
 - Younger pediatrics versus older pediatrics
 - Dialysis versus no dialysis
 - Priority for difficult dialysis access in pediatric candidates, as once these candidates lose this access, they will lose all access
 - Failed peritoneal dialysis (PD)

- Kidney-pancreas allocation should *not* have priority over pediatric kidneys, as there is no medical urgency score for pancreas
- Recommendation to designate one kidney to be allocated on the single kidney list, and then the other for multi-organ
- Recommendation that if the pediatric candidate had a longer waiting time than the multi-organ candidate, particularly for a kidney-pancreas, that the pediatric candidate receive priority
- Recommendation to stratify heart-kidney candidates who are stable on a ventricular assist device (VAD) versus pediatric candidates on dialysis with a high CPRA
- Recommendation to review data looking at:
 - Mortality rate for kidney-pancreas (KP) versus pancreas versus pediatric candidates
 - Kidney non-utilization rates
 - KDPI of multi-organ transplants versus pediatric recipient KDPI
 - Kidney after pancreas survival rates versus pediatric survival rates

One member remarked that high CPRA candidates should receive priority for multi-organ transplants, but that the question remains as to which high CPRA candidates should receive priority. The member noted that patients with a CPRA of 98 percent or 99 percent and higher may be appropriate, and that this cut off is negotiable. The member explained that these patients may only ever receive one kidney offer – one chance for transplant. The member continued that this makes a clear case for those candidates to receive high priority relative to multi-organ candidates. The Chair remarked that the CPRA cut off should mirror the priority currently given nationally to CPRA 100 and 99 candidates. The member responded that there is also priority for high CPRA candidates within 500 nautical miles versus 250 nautical miles. The member added that these definitions for high priority high CPRA candidates already exist. Another member agreed, noting from a pediatric perspective that there is an opportunity cost, particularly in terms of ethics. The member pointed out that CPRA 99 percent patients are receiving very few offers.

The member recommended modeling how many offers a typical extra-renal multi-organ candidate receives versus candidates with a CPRA of 98 percent. The member shared that priority should go to the person who is more disadvantaged in terms of realistic offers. The Chair summarized this member's statement, such that the data would show how many offers these high CPRA candidates receive compared to extra-renal multi-organ candidates.

A member pointed out that a highly sensitized multi-organ candidate should get priority as they are highly sensitized. The member noted that overall, highly sensitized patients should generally always have higher priority, particularly if they meet both the multi-organ and highly sensitized priority.

The Chair pointed out that the Committee will need to determine the CPRA cut off for prioritization against multi-organ extra-renal candidates. One member commented that this cut off should be CPRA 99 or greater. The member explained that the sensitized multi-organ candidate with no national sharing should receive higher priority than the kidney. The Chair asked if this was because those candidates will have access to a smaller pool of donors, and the member responded that this is because kidneys can tolerate more cold ischemic time and be shipped further than a heart or lung.

One member shared that it is rare for thoracic programs to consider highly sensitized patients, noting that these patients can't be desensitized as their transplant can't be planned, and these patients have poor outcomes when highly sensitized.

Staff shared data on the CPRA at time of match for next candidates on the kidney match run by kidney-alone recipient age. This analysis looked at the next candidate on the kidney match run for kidneys allocated to multi-organ candidates. Although CPRA of the next candidate at time of match was often 0

percent, there were about 373 cases where the next candidate on the match run had a CPRA, defined as 98 to 100 percent CPRA. A member remarked that this data is compelling, and underscores the importance of prioritizing highly sensitized candidates over non-sensitized multi-organ candidates. The Chair agreed, and noted that there seems to be some consensus and precedent for defining these candidates as CPRA 98 to 100 percent. A member agreed, and noted that this should be presented for public comment, but that this data shows a natural cutoff for exactly which patients are significantly disadvantaged. The member added that they believed the thoracic community would agree.

The Chair asked if extra-renal multi-organ transplant candidates should have priority over medically urgent kidney alone candidates. One member remarked that multi-organ kidneys candidates should not receive this level of priority over medically urgent kidney candidates, noting that the kidney medical urgency criteria is incredibly strict, and that these candidates are essentially a single blood clot away from dying. The member emphasized the importance of prioritizing kidney medically urgent patients. The member noted that the kidney medically urgent population is small enough that it would not impact multi-organ transplantation. Another member pointed out that medically urgent pediatric kidney patients do not currently receive additional priority in the medically urgent classification. The member added that dynamic allocation frameworks like continuous distribution will help benefit pediatric patients in this way.

One member pointed out that safety net priority is not included in allocation for kidneys with a KDPI 0 to 20 percent, in order to prioritize pediatric candidates and simultaneous kidney-pancreas. The member continued that an argument could be made to also exclude safety net priority or even multi-organ candidate priority in allocation for kidneys with a KDPI 21 to 34 percent, and have the standard kidney safety net be KDPI 35 to 85 percent.

The Chair summarized previous comments, noting that the Committee seems to agree that kidney alone medically urgent candidates should not be bypassed for multi-organ or pediatric candidates. A member agreed that medical urgency should have priority over multi-organ, but noted that the data regarding kidney medically urgent candidates and recipients raises questions about the actual mortality of patients listed at the kidney medical urgency status and how strictly those patients are selected. The member continued that the formation of the review boards may aid in making the criteria much stricter and to get at those candidates that are truly medically urgent. The member emphasized that medically urgent patients should be prioritized over multi-organ patients. Another member agreed, noting that the kidney medically urgent population is an inherently small group, and that most candidates who could meet this criteria typically die before receiving a transplant, or otherwise become ineligible for transplant. Another member agreed that the kidney medical urgency criteria is very strict, and so this population will remain inherently small. One member noted that it can be difficult to predict how long each dialysis access can be maintained, and shared that their program has seen patients who were dialyzed for more than 10 years via their last dialysis access.

The Chair wondered how many kidney medically urgent patients were removed due to being too sick.

Staff suggested that the Kidney Continuous Distribution framework could include a binary “high CPRA” attribute, which could be weighted highly enough to allow those candidates to consistently meet a composite allocation score cut off determined by the Committee.

One member asked if there was any specific categories of pediatric patients that should be considered. Another member remarked that all pediatric candidates should receive priority over adult multi-organ candidates. A member noted that pediatric patients with prolonged waiting time should be prioritized, pointing out that a year or more of dialysis is associated with increased mortality in younger children.

Upcoming Meetings

- November 9, 2022
- December 14, 2022

Attendance

- **Committee Members**
 - Lisa Stocks
 - Alden Doyle
 - Alejandro Diez
 - Shelley Hall
 - James Sharrock
 - Oyedolamu Olaitan
 - Paul Franklin
 - Peter Abt
 - Rachel Engen
 - Sandra Amaral
 - Valerie Chipman
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Katie Audette
 - Jonathan Miller
- **UNOS Staff**
 - Kaitlin Swanner
 - Katrina Gauntt
 - Erin Schnellinger
 - Kayla Temple
 - Kelsi Lindblad
 - Krissy Laurie
 - Matt Cafarella
 - Melissa Lane
 - Ben Wolford