OPTN Ad Hoc Multi-Organ Transplantation Committee
Meeting Summary
September 14, 2022
Conference Call

Lisa Stocks, RN, MSN, FNP, Chair

Introduction

The Ad Hoc Multi-Organ Transplantation (MOT) Committee met via Citrix GoToMeeting teleconference on 09/14/2022 to discuss the following agenda items:

1. Public Comment update
2. Liver-Kidney Project Update
3. New Project: Identify Priority Shares in Kidney Multi-Organ Policies
4. Project Sequencing
5. New Project Development: Identify Priority Shares in Kidney Multi-Organ Policies

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

1. Public Comment Update

The Chair reminded the Committee that public comment is currently open through September 28. Members are encouraged to review and provide feedback on public comment proposals.

2. Liver-Kidney Project Update

The Chair provided a brief update of the liver-kidney project. The Liver & Intestinal Transplantation Committee presented the project to the Policy Oversight Committee (POC) for project approval on September 12th. The POC decided that the Ad Hoc Multi Organ Transplantation Committee, as opposed to the Liver and Intestinal Transplantation Committee, should sponsor the project in order to provide a more consistent approach to developing multi-organ policy.

Project overview and considerations:

This project aims to expand the geographic area for simultaneous liver-kidney (SLK) allocation required sharing, to align with heart-liver and heart-kidney allocation, and so ensure more equitable access to transplant for SLK candidates. This project proposes that the kidney must be offered with the liver if the candidate is within 150 nautical miles (NM) with a median end stage liver disease (MELD) or pediatric end-stage liver disease (PELD) score 15 or greater or within 500 nautical miles and MELD/PELD 29 or greater or status 1A or 1B. To qualify for these required shares, the candidate must meet eligibility criteria for chronic kidney disease, sustained acute kidney injury, or metabolic disease.

This project will address three concerns:

- Donor availability differs across the country, and 150/250 NM may not provide sufficient access to kidney offers in more isolated areas
- Consistency: with simultaneous heart kidney (SHK) using 500 NM and simultaneous lung kidney (SLuK) using a composite allocation score of 28 or greater (which has distance built in), SLK circles should be larger to align with other organs

- OPO discretion: it can be difficult to get OPOs to offer kidney with the liver for SLK candidates that don't meet the required geographic allocation thresholds

There are several considerations for this project, including that the Committee had already identified a new project on kidney multi-organ transplant, which is tentatively slated for review by the Policy Oversight Committee in October. Also, the Liver & Intestinal Transplantation Committee has already identified participants from various committees to work on the liver-kidney project.

Summary of discussion:

One member remarked that there are two big issues for consideration with this project; the first, whether the Committee agrees with expanding the required SLK shares circle to 500 nautical miles, and the second, how this project can be sequenced with other work done by the Committee. The member remarked that there is a lot of emotion and drive in the OPTN Liver and Intestinal Transplantation Committee for this project, but that the Ad Hoc Multi-Organ Transplantation Committee will ultimately need to decide whether the expansion is appropriate. The member also noted that the Committee will need to determine whether this should be sequenced with Liver Continuous Distribution or prioritized for the upcoming public comment cycle. The Chair agreed, adding that data will be important to these discussions.

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

The Chair reviewed the proposal for the new Committee project *Identifying Priority Shares in Kidney Multi-Organ Policies*. The Chair reviewed the strategic plan alignment and key metric analysis.

Presentation summary:

At the August Committee call, the members expressed support for this project to improve equity and efficiency in multi-organ transplantation by providing more direction in policy on multi-organ allocation.

Proposal: establish an updated framework for multi-organ allocation that addresses:

- Required MOT shares versus single organ offer acceptance
- When kidneys should be offered to single organ candidates before multi-organ candidates
- How to determine which kidney to offer to which candidate, including laterality
- Promoting consistency in OPO practice while leaving flexibility for dynamic allocation circumstances

Challenges to be considered include:

- When binding organ offer acceptance conflicts with required MOT shares, such as due to a late turn down
- When kidneys should be offered to single organ candidates before multi-organ candidates
- How to determine which kidney to offer to which candidate, including laterality
- Allocation is not a static process – OPOs require some level of flexibility

The scope of this project will be limited to kidney shares for now, but future work could consider thoracic-liver required shares.

Key metrics include:

- Number and proportion of multi-organ candidates who receive multi-organ transplant pre- and post-policy
- Median waiting time to transplant for different multi-organ combinations pre- and post-policy
- KDPI of kidneys used in multi-organ allocations

- Additional metrics?

Project timeline:

- September/October 2022: Submit project form to HRSA and POC
- October/November 2023: POC and Executive Committee review/approval
- January 2023: Released concept paper for public comment
- August 2023: Submit policy proposal for public comment

Summary of discussion:

One member pointed out that the more allocation emphasizes and prioritizes waitlist mortality in non-renal organs, the more the pool of extra-renal multi-organ candidates expands. The member explained that this need for extra-renal multi-organ transplant ends up increasing waitlist mortality for kidney transplant candidates. A member identified the safety net as an option to mitigate that from occurring. Currently, the safety net is working well in for liver patients and will hopefully provide similar support to heart and lung patient upon implementation.[1]

A member suggested including metrics for kidney alone candidates that are similar to the ones proposed for multi-organ candidates, but solely focused on kidney alone candidates. The Chair suggested number of highly sensitized patients, or the number of patients that would receive a transplant that otherwise may not have. The member recommended looking into access and transplant rates for high calculated panel reactive antibody (CPRA), prior living donors, zero ABDR mismatch candidates, and pediatric candidates, as well as median waiting time and sequence of KDPI for these candidates, to mirror what could be considered high priority kidney-alone mandatory shares.

Staff asked the Committee if prior liver recipient kidney patients would be considered single-kidney recipients or multi-organ recipients for research purposes. Committee members agreed that safety net kidney transplants should be considered separate, single organ transplants.

4. Project Sequencing

The Committee discussed project sequencing for the *Identify Priority Shares in Kidney Multi-Organ Policies* project and the Simultaneous Liver Kidney Required Shares Expansion project, including a potential workgroup roster for the latter project.

Presentation summary:

How should the MOT Committee proceed with these two projects?

Recommendation: Workgroup develop SLK project for January 2023 public comment

- The Committee continues working on kidney MOT project while a Workgroup focuses on the SLK project
- Aim for August 2023 public comment for the kidney MOT project
- Committee will sponsor the SLK proposal, and so will vote on what goes out for public comment

Summary of discussion:

The Chair of the Policy Oversight Committee (POC) provided insight behind the POC's decision to move this project from the Liver Committee to the MOT Committee. The Chair of the POC explained that this

[1] OPTN Ad Hoc Multi-Organ Transplantation Committee, "Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation," June 2022. https://optn.transplant.hrsa.gov/media/npslvryi/establish-eligibility-criteria-and-safety-net-for-heart-kidney-and-lung-kidney-allocation_winter-2022-pc.pdf.

project expands on work that the MOT Committee is currently doing, and that the MOT Committee is well poised to take this project on, with a strong understanding of the multi-organ allocation policies that have been in development. The Chair of the POC noted that there were clear concerns with this project and the conduct of this project within the POC, and that this project needed to be in alignment with other MOT projects. The POC Chair recommended that this project be led by the MOT Committee, and that the majority of the project's development occur within the MOT Committee, similar to other Committee projects. The POC Chair noted that the members of this Workgroup could still be invited to these discussions, but that the main development should occur within the whole of the MOT Committee.

One member expressed confusion, pointing out that a workgroup dedicated to this project has already been developed. The member commented that the issue is simple, to increase the required share circle size to 500 nautical miles, to align with heart-kidney allocation policies. The member noted that this would not be many patients, just those patients who are currently disadvantaged in certain geographic areas. Another member responded, pointing out that the project is not quite as simple as changing the required share circle size, and citing that the POC had similar concerns with other populations that may be impacted. The member shared that the POC recommended submitting a data request to understand the issue further and spend the time to fully develop the project and ensure there are not any unintended consequences. The member noted that the MOT Committee, as the leader for this project, has a responsibility to develop this policy appropriately. Another member remarked that there are patients who are currently being disadvantaged by lack of alignment between heart-kidney and liver-kidney allocation policies, and noted that there are many members of the Liver Committee who would disagree with this approach. The member added that this project should not be delayed. The Chair responded that this project would not be delayed, and that currently, this project is expected to be released for public comment in January 2023, as long as data results can be sufficiently requested, prepared, and reviewed. The Chair explained that the policy change must be based on this data and that the data can help identify disadvantaged patients. The Chair added that timeline concerns are one reason why it makes sense for a workgroup to develop this project.

Staff clarified that the MOT Committee would still be sponsoring the SLK project, and that the workgroup would develop the proposal as recommendation for the Committee to review, discuss, and approve before sending out for public comment.

A member expressed concern regarding the makeup of the SLK 500 Workgroup roster, noting that increased kidney representation is needed. Another member agreed, adding that there need to be more kidney-specific MOT Committee representatives on the SLK 500 Workgroup, as well as other Committee representation.

One member remarked that there are always unintended consequences, and that even the simplest projects are not immune to unintended consequences. The member noted that it is important to develop this project appropriately, even if it pushes the project back a public comment cycle, in order to ensure this project is done right.

A member expressed support for having the MOT Committee sponsor the SLK Required Shares Circle Expansion project, and moving it forward through a workgroup. The member reiterated that it is important to thoroughly discuss this project to address potential unintended consequences.

5. New Project Development: Identify Priority Shares in Kidney Multi-Organ Policies

The Committee continued discussions to develop the *Identify Priority Shares in Kidney Multi-Organ Policies* project.

Presentation summary:

Possible framework: OPO must offer kidneys to certain kidney-alone candidates (such as kidney medically urgent, zero ABDR mismatch, 100 percent CPRA, certain pediatric candidates), then may proceed with offering kidneys off of other match runs (heart-lung, lung, heart, liver, kidney-pancreas), and then finally may proceed with offering kidneys to other kidney-alone candidates.

Summary of discussion:

One member commented that kidney carve out candidates should not be prioritized over critically ill multi-organ candidates. The Chair agreed that a cut off should exist, and asked where this cut off should be.

A member pointed out that there are highly sensitized kidney alone candidates who may never get more than one appropriate kidney offer. The member provided an example of a highly sensitized pediatric candidate who needs a second transplant; that patient and a critically ill heart-kidney candidate could be up for the same kidney offer. The member explained that, currently, the heart-kidney candidate would have priority for that kidney offer, even though the kidney-alone candidate may not receive another appropriate offer and the heart-kidney candidate could be eligible for a safety net kidney. The member shared that, in that scenario, it would make more sense for the kidney candidate to receive priority for the kidney. The member continued that the current multi-organ system does not give enough preference to highly sensitized and highly needy kidney candidates.

One member explained that they see two separate factors to consider with high priority kidney candidates: those who are "needy," and those who are difficult to match. The member continued that those "needy" patients are those who are medically urgent, and the argument could be made that a number of candidates fall into that category, including pediatric patients. The member further explained that those patients who are difficult to match are a little different, and that these patients are unlikely to get another appropriate offer for quite some time. The member remarked that these are two different factors, two different issues, with two separate solutions. The member explained that, for highly medically urgent kidney patients who have lost dialysis access and may not live a week, the solution isn't to fly them across the country, but to give them high priority for donor kidneys in their area, similar to highly medically urgent liver patients. The member continued that the solution is different for difficult to match, highly sensitized 100 percent CPRA patients – it could be more appropriate to fly these kidneys, as those patients may not get a similar chance to access transplant for several years. The member noted that one could make the argument that pediatric patients deserve a similar priority both nationally and locally. The member explained that, when considering which kidney alone patients need to compete with multi-organ shares, there are many different reasons that patient may need to do so; furthermore, some patients may only have one reason while others may have a combination of smaller reasons.

A member pointed out that many other countries' multi-organ transplant allocation policies will explicitly state that if one kidney is offered to a multi-organ candidate, the second kidney must first be offered to certain kidney alone candidates, such as pediatrics or highly sensitized, before it can be offered to another multi-organ candidate. The member suggested that the kidneys could be divided up between the two groups, since there are two kidneys. The Chair agreed, noting that this would address the issue of those who are highly medically urgent, versus those who may not get another offer for two years. Another member explained that highly sensitized patients may not get another offer for ten years, not two years, and that the lack of access is severe. The member asked the Committee where that line should be drawn. A member explained that, in current kidney allocation, 100 percent CPRA patients are given 202 points, the equivalent of 202 years of dialysis time. The member continued that this priority reflects the gravity of the scarcity of these matches, and that these patients still have trouble

finding good matches. The member pointed out that minority and historically disadvantaged populations are those that are most sensitized, and strongly urged the Committee to prioritize 100 percent CPRA patients. The member expressed support for a system where one kidney is offered to these patients, zero ABDR mismatch, and pediatric patients before it can be offered to another multi-organ candidate.

The Chair suggested that there could be an algorithm based on the type of candidate, to differentiate between those candidates that should absolutely receive the offer before a multi-organ candidate and those that could be considered for receiving the offer before a multi-organ candidate. The Chair explained that the language could include a caveat for one kidney to go to multi-organ and the other to first be offered to specific kidney candidates.

One member pointed out that the transition to continuous distribution presents a challenge, noting that policy will apply differently two years or a year from now because the language will be different. The member continued that it is difficult to decide when some organs have allocation points, and others have statuses, while all the organs transition to allocation points. The Chair responded that the Committee could instead focus on actual patient causes and medical statuses.

A member shared that the lung-kidney population is incredibly small, and that the lung transplantation community would not likely be concerned about mandatory single shares. The member added that, for the lung transplantation community, the allocation order is one of the more pressing multi-organ transplant topics, particularly between thoracic organs. Another member agreed, sharing that, rarely, OPOs are forced to figure out how to allocate between a primary heart-kidney, primary lung-kidney, and primary liver-kidney. The member added that choice of laterality must also be considered.

One member recommended looking into KDPI stratification, noting that organs from higher KDPI donors are not suitable for multi-organ transplant. The Chair agreed. Another member pointed out that most MOT recipients receive low KDPI kidneys. Another member agreed, but noted that not all MOT recipients receive very high quality kidneys, and that some utilized kidneys greater than 35 percent KDPI. One member explained that part of this is due to the nature of the other organs, pointing out that hearts and lungs have a limited organ base compared to other organs. The member continued that, by the nature of the organ, those donors are typically low KDPI donors. Another member pointed out that this is a factor in discussions about Kidney-Pancreas (KP) as well, as a large majority of kidneys utilized in KP transplants are less than 35 percent KDPI, due to the nature of the pancreas. The member continued that a policy determining the sequencing of multi-organ transplant versus kidney alone transplants will need to take into account the potential loss to the kidney community of higher quality kidneys versus the potential that there is a generally negative impact on multi-organ transplant if utilizing higher KDPI donor organs.

<u>Presentation summary:</u>

General project outline:

- Refine required kidney-alone shares
    - Consider if this could negatively impact KP/pancreas candidates
    - Consider how to incorporate kidney composite allocation score
    - Will discuss further on upcoming meeting with review of the Kidney and Pancreas Simultaneous Allocation Modeling (KPSAM) results
- Prioritization of kidney offers on other match runs
    - Should we dictate an order between heart-kidney, lung-kidney, liver-kidney, and kidney-pancreas offers?
    - Review medical urgency data and consider if additional data are needed

- Request and consider feedback from stakeholder committees
- Work through policy language and how to give OPOs both direction and flexibility

Summary of discussion:

The Chair asked the Committee how they felt the order should be dictated between the double organ allocations. One member shared that with continuous distribution, there seems to be shift toward greater priority for outcomes and post-transplant survivability. The member provided an example that, between a sicker patient and a highly sensitized or pediatric patient who may live longer, there seems to be a tendency toward prioritizing the later patient. The member noted that patients really react to outcomes data as well.

One member remarked that, in a future state, sequential transplant makes more sense than simultaneous, and the more frequently safety net is utilized and optimized, the easier it will be to defend allocating organs sequentially rather than simultaneously. The member explained that, for a heart or lung patient, that patient could receive and recover from their thoracic transplant and six months later receive a kidney transplant. The member shared that it is difficult to perform a simultaneous heart kidney transplant. The member noted that sequential kidneys will be easier to manage and to allocate. Another member agreed, noting that the lung transplantation community is experience a shift in preference towards sequential multi-organ transplantation, as the risk of kidney graft loss is considerable with simultaneous lung-kidney transplant.

A member asked if the outcomes of safety net for heart-kidney were different than those for liver, and noted that these outcomes could differ significantly. It was clarified that the heart-kidney safety net policy has not yet gone into effect. One member shared that there are a few patients for heart who have received a safety net kidney, and that it happened slightly more frequently in the old allocation system, where a heart recipient would receive a living donor kidney. The member explained that those recipients do well, but they weren't quite as sick as most heart recipients are now when leaving the operating room.

A member responded that it will be important to review safety net kidney outcomes data, as these outcomes might be different and it could be worth looking into and considering these differences. One member noted that this data was shared when developing the policy, and that heart recipients don't do quite as well. The member explained that part of the issue is that heart patients listed for transplant are typically very sick. The member agreed that the outcomes data will be important to review.

One member offered that the Committee should try to develop some sort of composite scoring system, such that the organs could be compared, with points based on different values and aspects. The member asked the Committee how they felt the deceased donor kidney waiting list is doing. The member noted that part of the solution is living donors and innovations with xenotransplant, but that the Committee needs to determine how they feel about the kidney waiting list today, in 2022. The member explained that, if short term life expectancy is the priority, multi-organ candidates will always have priority over kidney candidates because of dialysis. The member pointed out that the kidney waiting list is growing more than any other list, and it's growing quickly. The member remarked that the Committee has a responsibility to that patient population, not just individual patients, but the population as a whole.

Another member agreed, and reiterated that prioritizing waitlist mortality drives the need for extra-renal multi-organ transplant. The member suggested that potentially the Committee and the community could push back on that. The member explained that, potentially the heart transplantation community should be pushing patients to durable ventricular assist devices (VADs). The member remarked that the community needs to create more balance between waitlist mortality and other priorities going forward.

The Chair noted that the Committee could ask other stakeholder committees for feedback on the concept of one kidney going to multi-organ transplant candidates and the other to single-kidney candidates.

A member remarked that the first question people will ask is in what order the multi-organs should be allocated. The Chair offered that the policy could say that allocation begins with heart or liver kidney, because these patients are the most medically urgent, but that one kidney should be put aside for kidney along candidates. Another member recommended that the second kidney be reserved for kidney or kidney-pancreas.

One member pointed out that having a binary for one kidney to go to MOT and the other to single-kidney transplant may not fit well with continuous distribution, and that this moves away from the benefit of that complex system. The Chair noted that continuous distribution is not yet in place for kidney allocation. Another member remarked that continuous distribution may not be as helpful here, as a lung composite allocation score of 87 may not necessarily be equivalent to a kidney composite allocation score of 87. The member continued that these scores may mean different things in terms of waitlist mortality, estimated post-transplant survival, and other values, and that they may not directly correlate across the organs. The member noted that, eventually, some sort of weighting system could be worked out, but that probably couldn't exist until everything is in place and there are a few years of data available. Another member agreed.

Presentation summary:

Medical urgency data considerations:

- Goal: compare medical urgency between kidney multi-organ candidates
- Some data is available on kidney MOT candidates in different timeframes, but not a comprehensive review in the same timeframe
- Six-month monitoring report on the *Clarify Multi-Organ Allocation Policy* will be available this fall

Medical urgency data questions:

- How do we define multi-organ candidates for the purposes of examining medical urgency?
    - Limit to dual organ candidates, and exclude candidates registered for 3 or more organs?
    - Do we include candidates registered for multiple organs who receive a single organ transplant? Do we include those who later received a safety net kidney?
- How do we define medical urgency?
    - Based on heart/lung/liver status? What about pancreas?
    - Waitlist mortality?
- Timing of data request?
    - Committee may want to wait until after review of KPSAM results and six-month monitoring report

Summary of discussion:

The Chair expressed support for looking into outcomes information, and suggested waiting until modeling was available.

One member recommended looking into data at how often an MOT candidate receives a kidney that a high-CPRA candidate was back up for. The member noted that these candidates would be considered immunologically high risk. Another member agreed. One member noted that this data is typically available for pediatric patients. A member reiterated another member's point, noting that access for

other candidate types could be addressed in other ways, but that highly sensitized kidney candidates may only ever receive 1 or 2 medically appropriate kidney offers.

One member asked how that could be measured, particularly given that most people will input a provisional yes before fully evaluating an offer. The member asked if every candidate past the MOT candidate would be considered a candidate that lost out on that offer. Another member explained that, utilizing the match run data, one could go back and look at every kidney transplanted as part of an MOT transplant and see how many highly sensitized candidates would have been eligible to receive that kidney.

Staff noted that utilizing match run data could be very involved, and would require significantly more time to develop the data report.

A member wondered if there were any models that could predict which donors would be MOT donors. The member noted that a one-size-fits-all policy could result in a significant amount of back-and-forth and allocation inefficiency for OPOs between different match runs. The member explained that there will need to be some process that takes into account allocation efficiency, particularly when it comes to late declines.

Upcoming Meetings

- October 12, 2022
- November 9, 2022
- December 14, 2022

Attendance

- **Committee Members**
  - Lisa Stocks
  - Alden Doyle
  - Alejandro Diez
  - Shelley Hall
  - Jennifer Prinz
  - Jim Sharrock
  - Marie Budev
  - Nicole Turgeon
  - Peter Abt
  - Rachel Engen
  - Vince Casingal
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Katie Audette
  - Jonathan Miller
- **UNOS Staff**
  - Kaitlin Swanner
  - Erin Schnellinger
  - Holly Sobczak
  - Matt Cafarella
  - Meghan McDermott
  - James Alcorn
  - Kayla Temple
  - Ben Wolford
  - Joann White
  - Keighly Bradbrook
  - Kim Uccellini
  - Krissy Laurie
  - Laura Schmitt
  - Matt Belton
  - Melissa Lane
  - Paul Franklin
  - Rebecca Fitz Marino
  - Ross Walton
  - Sara Langham
  - Sarah Booker