OPTN Ad Hoc Multi-Organ Transplantation Committee
Meeting Summary
April 12, 2023
Conference Call

Lisa Stocks, RN, MSN, FNP, Chair

Introduction

The Ad Hoc Multi-Organ Transplantation Committee met via Citric GoToMeeting teleconference on 04/12/2023 to discuss the following agenda items:

1. Public Comment Analysis Simultaneous Liver-Kidney (SLK)
2. SLK Proposal Update and Vote
3. Identify Priority Shares in Kidney Multi-Organ Transplantation

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

1. Public Comment Analysis Simultaneous Liver-Kidney (SLK)

The Chair presented and provided an analysis of the public comment results for SLK.

Data summary:

Public comment for SLK began on January 19, 2023, and ended on March 19, 2023. From the 232 commenters and six OPTN Committees, the overall sentiment score was a 3.5 (out of 5). Data shows that most states, and Puerto Rico, participated in the public comment. High levels of participation took place at regional meetings and in early February when the proposal first went online. Data on the average sentiment by member type and region was reviewed with the Committee.

SLK Public Comment Themes:

- Kidney-Alone Candidates:
  - There was a concern across the community that Kidney-Alone candidates will be bypassed
  - This has been mentioned at every regional meeting and by the majority of public commenters
- Pediatric Candidates:
  - There was a broad concern across the community relating to access for pediatric candidates
  - There was little delineation in comments between single-organ and MOT pediatric candidates
- Geographic and Cold Ischemic Time (CIT)
  - Some regions were concerned that expanding SLK puts them at a disadvantage
  - Increased CIT because they would be traveling more frequently

Summary of discussion:

The Committee further discussed the results of the public comment. An OPTN Contractor staff member stated that the proposal had been viewed by a lot of people. In addition, many people provided comments and contributed to the total sentiment score. A staff member also discussed how a total

sentiment score of 3.5 was good. A 3.5 out of 5 indicated that the proposal was most likely popular and well received. Most importantly, the total sentiment score means that the proposal was not voted down by the community.

On the breakdown of sentiment score by member type, a staff member pointed out that most respondents supported or strongly supported the proposal compared to those who strongly opposed. When looking at the graphical breakdown of sentiment score by region, a committee member mentioned how the geographic areas that this policy would affect most, were the regions that did not have as high a level of participation. In addition, these areas near the middle of the country received lower sentiment scores. However, staff also noted that there was a lower response rate amongst these states. The feedback indicated that these states were specifically concerned about geography. Region 10 also had a lower sentiment score of 3.2. The Chair stated that Region 10 is one of the areas in which there is a projected increase in SLKs.

Next steps:

The Committee will consider the feedback provided and begin creating specific policy language for the other project they were working on.

2. SLK Proposal Update and Vote

The Chair provided the Committee with an update on the SLK proposal and shared what the language will look like.

Data summary:

According to feedback received during public comment, there are no major language changes needed, however, there is one technical change that must be made. This change is specifically concerned with the current policy language that lists status 1B for allocation. This is unnecessary as status 1B is specific to pediatrics who are already covered in the first criteria. The policy would be amended to specify that adult status 1A is being referenced in the fourth criteria.

Summary of discussion:

The Committee was asked to vote to send the SLK Proposal to the OPTN Board in June.

Yes: 10, No: 0, Abstain: 1

Next steps:

The SLK proposal and its revisions will be sent to the OPTN Board of Directors for consideration at their June 2023 meeting.

3. Identify Priority Shares in Kidney Multi-Organ Allocation

The Chair reviewed and led the Committee in conversation regarding priority shares in kidney multi-organ allocation.

Data summary:

The three main concepts that were discussed included the allocation of kidneys from the same donor in which one kidney would be offered to a multi-organ transplant (MOT) candidate and the other to a kidney-alone candidate, prioritization of MOT combinations, and the choice of left vs right kidney. The three topics are being addressed because the community felt more clarity in policy was needed.

Summary of discussion:

The Chair asked the Committee for feedback on three different questions and ideas regarding the allocation of two kidneys from a single donor. The concepts that were introduced are outlined below.

- One kidney must first go to an MOT candidate, one kidney to a single-organ transplant (SOT) candidate
    - Would kidney-pancreas (KP) candidates be allocated via the MOT or SOT slot?
- At what point can the OPO offer the non-kidney single organs?
    - If there is a late turndown, does the OPO then have to offer to MOT candidates of the type of organ available? For example, if there is a simultaneous liver-kidney (SLK) late turndown, then is an offer made to SLK candidates? Or is offering to SOT candidates acceptable?
- What if a donor only has one transplantable kidney?

A member from the Pancreas Committee stated that pancreas patients should get priority because they usually originate as kidney patients and mortality is increased for diabetics relative to kidney-alone candidates. The committee member also mentioned that the general sentiment is that highly sensitized, pediatric, and previous organ donors meet criteria. In addition, many groups, such as pediatrics, want access to younger, more ideal donors. Therefore, it is advised that the one-to-one allocation stipulation may not be the best option. The Chair responded and said that the Committee could also consider different ways to look at the allocation categories.

A Committee member suggested that the group consider and remember the population of 18–35-year-olds. Since the situation concerns better quality organs, young adults tend to fall within the top 20% for post-transplant survival. The Chair questioned whether this age consideration was already in the allocation scheme and if they receive more points. The member responded and said that, generally, young adults would be in the Sequence A bucket for kidneys with a Kidney Donor Profile Index (KDPI) less than 35.

A member then questioned which organ would receive priority in MOT vs MOT cases and who exactly would make that decision. They also stated that even though allocating kidneys to KP patients increases the number of pancreases transplanted, there still must be geographical limitations to balance higher instance of organ denials. Despite these cases, the commenter expressed support for preferential treatment toward highly sensitized KP patients because of the well-known benefits of KP transplantations. However, they still suggested there be a balance regarding the zone where KPs are prioritized compared to kidney-alone patients.

A different committee member had asked if the denial of the pancreas for KP patients was common. In addition, they mentioned that even if the originating Organ Procurement Organization (OPO) must reallocate the organ, younger patients can usually tolerate an extended cold ischemic time (CIT). A different Committee member explained that, in these cases, it becomes a judgement call regarding whether the pancreas will go back or not. However, it is important to note that if the organ does go back to the OPO, it is doing so with additional CIT. The added CIT is not fair to the next patient on the OPTN Waiting List. The commenter also adds that there is not a lack of available pancreases to be transplanted but there is a lack of willingness to accept a transplantable pancreas.

On the matter of pancreas transplants, a committee member mentioned that there are major limitations with the donor surgery. More specifically, if they wanted to be able to allocate more pancreases, then a better job needs to be done when taking out the organ. They explained that many people will state they want the pancreas but will not go out for its recovery. Then, once the organ is

procured and presented to the center, the pancreas is often declined because they are not satisfied with its recovery. The commenter suggested there be a local infrastructure to improve this problem. Additional solutions may include requiring OPOs to have at least one competent pancreas surgeon, and a second option might be to give priority to local programs to eliminate the long travel and cold time.

In addition, a committee member stated that factors such as a candidate's Model for End Stage Liver Disease (MELD) score or time on dialysis should contribute to their priority. If a patient has a MELD of 40 and a Status 1 heart, it may be hard to take away that kidney unless there was a highly sensitized or pediatric candidate. The Committee member also added that there is a way to differentially say the need for those who are on dialysis and those who are not on dialysis. For example, the SHK listings that are on dialysis may get more priority or Status 1 compared to those coming through the chronic kidney disease pathway and not yet on dialysis. When looking at the data, in terms of benefit, the worse a patient's renal function is after doing a multi-organ transplant, the more the benefit there is from the kidney. On the flip side of that, there is more they can do with the safety net system compared to a single transplant event.

The Chair asked the Committee if they preferred to develop language that would allocate one kidney to an MOT candidate and the other to an SOT candidate. A kidney representative stated that they thought this proposal was great, however, it might not do as well in public comment because the prioritization of different MOT cases had not yet been decided on. The commenter also suggested that points be considered in these cases, as it is for the KP list, since there are situations in which two MOT allocations might be appropriate.

The Chair of the Committee agreed with the idea and mentioned how this proposal would take out some of the randomness that had been indicated in feedback. The Chair said they could revise the process to allocate one kidney to an MOT candidate and the other to the SOT candidate, unless there are two MOT candidates identified by a certain point system. The Chair then acknowledged that the next question the group would have to answer is when this decision should be enforced and how far down the OPTN Waiting List they should go before offering to the kidney list.

A Committee member added that they also agreed that the initial allocation scheme proposed would be too simple. The downfall of the original one kidney to MOT and the other to SOT proposal does not consider how sick certain MOT candidates could be. The commenter also adds that using the new continuous distribution point system to balance these situations makes more sense. A Committee member pointed out that a challenge to this proposal would be that not all organs are on the continuous distribution system yet. More specifically, OPOs and centers would not know how to weigh a SHK vs kidney points based on continuous distribution because everyone is not on the same system.

A Committee member then explained that the concern that people are raising in public comment is that the current system prioritizes MOT candidates over any other candidate. Therefore, the member recognizes that there is a need for a more nuanced and balanced approach. Within this allocation scheme, it may work to offer the second kidney first to specific categories, and if they deny, they can then look to allocate to the MOT list. On the matter of nuancing KPs, KPs would receive a certain priority on the MOT list and on the second kidney-alone list as well but at a more specified position. This would allow KP patients to have some sort of priority but would also ensure they are not always ranked higher than kidney-alone patients.

A Committee member added that they envisioned kidney allocation to be based on primary with choice and primary without choice. This commenter further explains that the Committee should come up with a list that is a hybrid between continuous distribution and current allocations. This list could determine that first choice would be for SHKs up to a certain status or points, SLKs with a MELD greater than 35,

sequence 5 KP, pediatrics, then the kidney-alone candidates. This would allow OPOs to know who gets first choice of kidney and who is the backup. This Committee member also added that OPOs should have to be required to offer organs two hours before the operating room (OR) and not be allowed to hold them for a backup. OPOs sometimes hold kidneys for possible KP or SLK candidates, however, this makes the process confusing, time consuming, and expensive for kidney-alone patients.

A Committee member explained that even if extra renal organs and kidneys are simultaneously placed, there is a certain point before recovery in which the OPO would know if the kidneys were allocated. At that time, if a kidney has not yet been placed, the OPO may call kidney programs to make them a primary. If allocation circumstances change, OPOs are not penalized for honoring the binding agreement to allocate to the primary kidney program. For example, if the first SLK candidate declines the organ, the OPO may offer the kidney to the primary and keep the next SLK candidate as a backup.

The Chair explained that the Committee should not specify a time in which this must take place and should leave the decision to the OPOs. If OPOs are following the guidance for multi-organ transplantations, the primary status for kidney-alone programs should be documented. A Committee member summarized that the underlying point was that even if circumstances change prior to going into the OR, OPOs should not rescind offers made to the identified primary status programs. The Chair agreed and expressed that this would be a patient care issue and practice that they should not do.

The Chair asked the Committee what should happen if a donor has only one transplantable kidney and if the decision should be left to the OPOs. A member responded that it is important to provide guidance for OPOs regarding first and second choice because there may be situations in which they do not know that one kidney is not transplantable until its recovery. A Committee member also added that there are instances in which the kidney is deemed non-transplantable, the organ is offered to a program, and then the program transplants the previously identified "non-transplantable" kidney. A Committee member also suggested that the allocation approach for cases in which only one donor kidney is available should be the same as the normal MOT and SOT kidney allocation. The Chair agreed and said that this would allow the process to be consistent.

The Committee member also asked the group to consider what would happen if the operation had started before or at the same time as the donor surgery, but they suddenly realize that there is only one transplantable kidney. Would the OPO have the authority to allocate the kidney to the person who is already being operated instead of to the first person on the OPTN Waiting List? Another Committee member added that it may really come down to choice vs no choice. The Chair responded and said that even though this is a different kind of conversation, it should still be discussed further.

The Chair asked the Committee for feedback on a few different questions and ideas regarding the prioritization of the different MOT kidney combinations. The concepts that were introduced are outlined below.

- Public Comment Feedback: Candidates who need three or more organs are more disadvantaged
- How to prioritize heart vs lung vs liver kidney combinations
    - Based on relative OPTN Waiting List mortalities of the combinations? Post-transplant survival?
    - Based on their order on the kidney OPTN Waiting List?
        - Many priorities were brought up by the community (high CPRA, pediatrics, and previous living donor) which are already prioritized on the kidney match run

The Chair stated that candidates that need three or more organs are rare, however, the allocation process can be very difficult. Therefore, the Chair questioned where in the sequence these candidates would go to receive a kidney compared to MOT combinations. To answer the proposed question, the

Committee would need data from the OPTN Waiting List for different MOT combinations they would also need to identify which organ would be driving allocation.

The Chair then proposed that if the Committee could come up with a hierarchy that prioritized the different MOT combinations, they would then be able to address cases of three organ candidates without formally addressing it in policy. A Committee member agreed and said that even though the other policies would take care of these instances, the data would be helpful to determine what the MOT combinations look like right now. Considering that there are only 10-20 three organ combination cases per year, properly prioritizing SHK, SLK, and SLuKs should not disadvantage these three organ candidates.

The Committee Chair asked members if the approach that considered dialysis vs non dialysis was already captured in the allocation sequence and point system for SHK and SLK. A Committee member said no this was not. Another Committee member explained that the flip side to eliminating a kidney for a patient not on dialysis is that a program may decline the primary organ entirely. Programs might think that they should wait to accept an offer with both organs, however, this could disadvantage the patient. The Chair also said that the Committee would need to identify the very sick, multi-visceral candidates that they would prefer to give both kidneys to.

Next steps:

The Committee agreed to continue these discussions at future meetings.

Upcoming Meeting(s)

- May 10, 2023, 3PM ET

Attendance

- **Committee Members**
    - Lisa Stocks
    - Peter Abt
    - Sandra Amaral
    - Vince Casingal
    - Christopher Curran
    - Alden Doyle
    - Rachel Engen
    - Shelley Hall
    - Heather Miller-Webb
    - Oyedolamu K Olaitan
    - James Sharrock
- **HRSA Representatives**
    - Shelley Grant
- **SRTR Staff**
    - Katherine Audette
- **UNOS Staff**
    - Alex Carmack
    - Courtney Jett
    - Matt Cafarella
    - Julia Foutz
    - Paul Franklin
    - Sara Langham
    - Meghan McDermott
    - Laura Schmitt
    - Kaitlin Swanner
    - Ross Walton
    - Ben Wolford