

**OPTN Ad Hoc Multi Organ Transplantation Committee  
Simultaneous Liver-Kidney Workgroup  
Meeting Summary  
November 7, 2022  
Conference Call**

**Lisa Stocks, RN, MSN, FNP, Chair**

## **Introduction**

The Simultaneous Liver-Kidney Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 11/7/2022 to discuss the following agenda items:

1. Project Background and Recap of Last Meeting
2. Data Request Results
3. Develop Recommendation for OPTN Ad Hoc Multi-Organ Committee

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

### **1. Project Background and Recap of Last Meeting**

The Chair reviewed the project background, timeline, and a summary of discussions at the Workgroup's last meeting.

#### Presentation summary:

This project was recommended by the OPTN Liver and Intestinal Transplantation Committee, and aims to expand the geographic area for required simultaneous liver-kidney (SLK) allocation to align with simultaneous heart-kidney (SHK) allocation and ensure more equitable access to transplant for SLK candidates, such that the kidney must be offered with the liver if the candidate is:

- Within 150 nautical miles (NM) and a Model for End-stage Liver Disease (MELD) score or Pediatric End Stage Liver Disease (PELD) of 15+
- Within 500 NM and MELD/PELD of 29+
- Within 500 NM and Status 1A or 1B

Current simultaneous liver-kidney allocation policy states:

- Kidney must be offered with the liver if candidate is:
  - 150 NM: MELD/PELD 15+
  - 250 NM: MELD/PELD 29+
  - 250 NM: Status 1A or 1B
- Candidate must meet eligibility criteria for at least one of the following:
  - Chronic kidney disease
  - Sustained acute kidney injury
  - Metabolic disease
- The OPO can then do either:
  - Offer liver and kidney to candidates meeting SLK criteria (outside of circle sizes and M/P thresholds)
  - Offer liver to liver-alone candidates and kidney to kidney-alone candidates

Current simultaneous heart-kidney allocation policy states that the kidney must be offered with the heart if the candidate is within 500 NM and:

- Heart Adult Status 1, 2, or 3
- Any active pediatric heart status

The simultaneous heart-kidney policy pending implementation will require candidates to meet eligibility criteria for chronic kidney disease or sustained acute kidney injury. The eligibility will be expanded to include Heart Adult Status 4 and 5 patients. The 500 NM circle was selected for heart kidney to align with heart allocation classifications.

Previously, the Workgroup discussed:

- Donor availability varies for different transplant programs
  - 250 NM might be sufficient in some areas but not in others
- Many organ procurement organizations (OPOs) agree to allocate the kidney with the liver for candidates meeting SLK medical eligibility criteria outside 250 NM, but not all do
- Kidney-after-liver safety net can provide expedited access to kidney transplant for liver recipients but some liver recipients are too sick post-transplant to make it back to kidney waitlist (this is not captured in OPTN data since those patients do not make it back to the waitlist)
- Some discussion that candidates meeting SLK medical eligibility criteria should have access to liver and kidney regardless of MELD/PELD score or NM distance
- Concern that expanding access to SLK transplant will decrease access to kidney-alone and pancreas-kidney transplant (especially for pediatric and high CPRA candidates)

The Workgroup aims to send this project out for the January 2023 Public Comment cycle.

#### Summary of discussion:

The Workgroup had no questions or comments.

## **2. Data Request Results**

Staff presented the results of the Workgroup's data request, which was submitted at their last meeting in September.

#### Data summary:

The purpose of this data report is to quantify the extent of variation in donor availability for SLK transplants within 250 NM versus 250-500 NM of donor hospitals.

The following metrics were analyzed to understand overall volume and volume by distance:

- Number of candidates listed (SLK and SHK)
- Proportion of candidates that received transplants (SLK and SHK)
- Number of additions that received transplants by
  - Lab MELD/PELD score at transplant (SLK)
  - Allocation MELD/PELD score at Transplant (SLK)
  - KDPI of Donor Kidneys (SHK and SLK)
- Average number of candidates waiting
- Average number of transplants performed
- Average number of removals for death/too sick

Volume by distance utilized a specific set of metrics built from averages of candidates waiting, removals for death or too sick, waitlist additions, and transplants.

- Average within 250 NM of the donor hospitals:
  - SLK removal to waiting ratio: 17.8
    - 42.30 removals for death or too sick to transplant
    - 237.3 candidates waiting
  - SLK transplant to waiting ratio: 54.5
    - 237.3 waitlist additions
    - 129.3 transplants
  - SHK removal to waiting ratio: 12.8
    - 12.51 removals for death or too sick to transplant
    - 97.8 candidates were waiting
  - SHK transplant to waiting ratio 61.1
    - 97.8 waitlist additions
    - 59.8 transplants
- Average between 250 and 500 NM of the donor hospitals:
  - SLK removal to waiting ratio: 17.3
    - 68.61 removals for death or too sick to transplant
    - 397.2 candidates waiting
  - SLK transplant to waiting ratio: 56.3
    - 397.2 waitlist additions
    - 223.8 transplants
  - SHK removal to waiting ratio: 12.8
    - 19.14 removals for death or too sick to transplant
    - 149.5 candidates waiting
  - SHK transplant to waiting ratio 61.3
    - 149.5 waitlist additions
    - 91.7 transplants

Assuming that the SLK transplant to waiting ratio seen under the current 250 NM circle remained the same when the circle is expanded to 500 NM, the average number of SLK transplants that *could* occur between 250-NM if the required share circle size had been 500 NM instead of 250 NM can be estimated.

- Assumption: The transplant to waiting ratio under current 250 NM circle is the same between 250-500 NM
- Estimated number of SLK transplants at 250-500 NM based on the transplant to waiting ratio seen at 250 NM: 216.4
- Actual transplants within 250-500NM: 223.8
- Estimated average additional transplants within 250-500 NM of a donor hospital: -7.4
  - Estimates varied by region from -25 to +17
  - SLK transplants were estimated to increase in Regions 3, 6, 7, 8, and 10
  - The analysis estimated negative transplants in Regions 1, 2, 4, 5, 9, and 11
  - It is critical to note that areas where the number of SLK transplants are estimated to decrease simply indicate areas where OPOs already share SLKs between 250 and 500 NM. **SLK transplants are not actually expected to decrease for these regions.**

Conclusion:

- About half of SLK candidates listed two years after acuity circles implementation are transplanted in that timeframe, similar to SHK candidates
- The majority of SHK recipients received a kidney with a KDPI of 20% or less while 38.84% of SLK recipients received a kidney with a KDPI of 20% or less.

- The majority of SLK recipients had an allocation MELD or PELD score of 30 or above at transplant (61%)
- The overall removal-to-waiting ratio for SLK was higher than that for SHK, regardless of distance for candidates removed for death or too sick
- Candidates listed for an SLK had a lower transplant- to-waiting ratio compared to candidates listed for an SHK
- When applying the 250 NM SLK transplant-to-waiting ratio to the 250-500 NM range, the estimated average number of SLK transplants would be similar to what is currently observed, although this prediction varies by region

Summary of discussion:

The Chair reiterated that the analysis does *not* actually project a decrease for those regions with a negative estimated number of additional transplants. The Chair explained that those regions with a negative estimated number of additional SLK transplants are simply those where OPOs are *already* allocating SLKs outside of the 250 NM range, where they are permissible. The Chair continued that the focus is to show those regions where OPOs are generally not sharing SLKs outside of 250 NM, which is where there is an expected increase if required shares are expanded to 500 NM. The Chair pointed out that Region 6 and Region 8 are estimated to see the largest increases in additional SLK transplants, and that these regions encompass large geographic areas.

One member remarked that this data proves that the vast majority of OPOs are already sharing SLKs between 250 NM and 500 NM, and that this is the right thing for OPOs to do. The member shared their experience in Region 8, where frequently the OPO will offer the liver without the kidney to a high MELD SLK patient. The member recounted that the concern from the Kidney Committee was that this policy change could potentially redirect many kidneys away from kidney-alone patients, but that this data shows that there will not be a huge net difference, as the vast majority of OPOs are already allocating SLKs within 500 NM. The Chair agreed that this data is helpful and encouraging.

The member argued that the SLK circle expansion makes sense, as it is logical that OPOs should *not* be put in a position where they may make a medical decision for the patients they are allocating to. The member continued that clinicians need to be the medical decision makers, and that a patient who meets criteria for an SLK should receive one. The member explained that the leading determinant of poor transplant outcomes is the presence of renal failure for any organ transplant. As such, for an OPO *not* to offer the kidney to a qualifying SLK patient is to significantly disadvantage that patient in terms of long term survival.

A member noted that, based on the analysis, most OPOs are already allocating outside of 150 and 250 NM. The member described anecdotal experiences of OPOs declining to offer the kidney with liver outside of 250 NM, so SLK allocation outside of 250 NM is certainly not uniform. The member continued that the data shows it is not expected to be a huge net difference in where people are getting the livers. The member pointed out that the data shows that even without a policy requiring SLK allocation within 500 NM, most patients still have pretty good access to SLK. The member shared that, as a member of the kidney transplantation community, they don't feel the need to push back on this policy change, and that it makes sense to align the allocation circles for SLK and SHK. The member pointed out that there are other opportunities for protecting access to kidneys for certain kidney-alone candidate populations, but that restricting SLK allocation is not the appropriate way to achieve that. The member expressed support for aligning the SLK allocation circles with those in SHK allocation.

Staff confirmed the member's understanding, adding that the data does not show a large net change, and that those regions with a negative estimated additional transplants would not likely see a decrease.

Staff continued that this data shows that programs in those regions will likely continue to perform as they have before. Staff explained there may be an overall small addition to the number of SLK transplants performed, and expanding the required share circle to 500 NM may not change how many transplants are performed, but rather who is receiving those transplants.

One member asked how this policy change would impact continuous distribution or vice versa. Another member responded that this multi-organ allocation would not be affected by the transition of kidney allocation to continuous distribution, and that it is not likely that this policy would need to change again in six months. The member pointed out that SLKs are allocated based on liver allocation, not on kidney allocation. Staff confirmed that this project would not impact kidney continuous distribution.

A member provided some historical context, sharing that when SLK allocation first went into effect, there was a complaint against the liver transplantation community that too many kidneys were being allocated to and transplanted with SLKs, as there were no guidelines or guardrails. Then, the OPTN Liver and Kidney Committees developed SLK eligibility criteria to help establish guardrails against overuse of SLK transplantation. The member continued that when liver allocation transitioned to acuity circles, the Liver Committee determined that 150 NM was a good surrogate for donor service area (DSA) and that 250 NM was a good surrogate for the region. The member commented that this works fine in New York, Philadelphia, or Boston, where population density ensures decent access to livers and kidneys, but that there is aberration for programs in less population dense, larger geographic areas. The member continued that this policy alignment should be done now, as opposed to waiting for liver continuous distribution, because the transition to liver continuous distribution is realistically three years away by the time the proposal could be implemented. The member shared that they had previously worked in Region 1, and upon moving to Region 8, they were able to see the unintended consequences of this policy regionally. The member expressed concern about the role of OPO discretion in determining who receives SLK offers. The member explained that if a physician decides that a patient requires an SLK and qualifies based on the medical eligibility criteria in policy, then the patient should receive an SLK offer, and a non-physician at an OPO should not be able to make that decision for the patient. The member concluded that the regional variation is an unintended consequence of the original policy, and this change is a simple fix with data to show there is little expected impact on the kidney community.

One member agreed that these numbers are reassuring in regards to potential impact on the kidney transplantation community. The member asked, if most OPOs are sharing the SLKs within 500 NM, how the data can show an estimated net negative. The member pointed to the wide variability between regions. Another member pointed out that this would actually be a net positive of 40 or 50 SLK transplants in a year. Staff agreed, noting that Region 9 would not actually be expected to perform less SLK transplants, but that Region 7 would likely do about 16 or so more transplants. Staff explained that regions with negative numbers are already perform a good number of SLKs in that 250 to 500 NM range, and are already exceeding the expectation for what the transplant to waiting ratio used. Staff continued that the interpretation of about 40 or so additional transplants is more accurate than the negative 7 developed by the equation. Another member noted that this is based on that ratio, and that they would not expected Region 8 to do 17 more SLKs, but instead just a handful more SLKs a year, based on how many SLKs are refused in a year. The member continued that the absolute number is less important than the trend, which shows just a slight increase in the number of SLKs nationally. The member continued that most OPOs are sharing beyond 250 NM already, which is the right thing to do.

A member agreed that this data proves the Workgroup's point, and it is ultimately not surprising. The member pointed out that most OPOs are sharing permissible SLK shares, and asked if guard rails will need to be added regarding permissibility if the mandatory share circle is expanded to 500 NM. The member explained that expanding the mandatory share circle will create an area of policy where SLK

shares outside of 500NM are permissible, and this could introduce regional variability again. The member asked how the policy could be written in a way that OPOs are not in a position to decide whether or not to share at 502 NM. The member continued that the new policy could still allow for this regional variability, albeit with a smaller pool of SLK patients. The member noted that, if the policy continues to be permissible versus required or not eligible, there will continue to be regional variation between OPOs in sharing beyond 500 NM. Another member pointed out that liver continuous distribution will break down arbitrary distance barriers, and noted that making SLK allocation permissible beyond 500 NM will be more consistent with continuous distribution than making it not permissible. The other member responded that liver continuous distribution is still 3 years away, to an earlier point. A member noted that these circles will not be utilized in continuous distribution, and instead proximity points will likely play a role.

The other member explained that the Workgroup should consider the repercussions of allowing permissibility and the resulting variability between OPOs and regions. The Chair expressed support for maintaining permissibility. The member noted that the permissibility will continue to be applied differently in different areas, just like it is now.

### **3. Develop Recommendation for OPTN Ad Hoc Multi-Organ Committee**

The Workgroup discussed whether to recommend aligning SLK circle sizes with heart-kidney allocation circles, thereby expanding the SLK allocation circle to 500 NM.

#### Summary of discussion:

Staff asked if the Workgroup had any additional questions, comments or concerns. Staff also asked the Workgroup if the data request addressed the concerns raised and whether there could be other unintended consequences. Staff asked for any other considerations for the Workgroup.

One member expressed support for moving forward with the recommendation, noting that this will provide good guidance for OPOs. The member pointed out that the first iteration of continuous distribution will likely still need some limit on the distance for required shares, as not all the organs will be in continuous distribution yet. The member continued that it will still be necessary to sequence multi-organ allocation. The member commented that there needs to be a point where there is a hard stop in allocation to SLK and SHK patients, and outside of that will be up to OPO discretion. The member continued that the benefit of this is that there will be less OPO discretion, and that this could potential encourage liver utilization. The member explained that a patient who needs a liver and a kidney could potentially accept a liver that others have declined at a greater distance. The member continued that this is why the discretion outside of 500 NM is useful.

A member remarked that the data supports moving forward with the recommendation. The member expressed support for limiting OPO discretion, and noted that there should be more consistency across the country and regions. The member noted that there needs to be a good post-implementation monitoring plan to ensure the actual numbers are in alignment with the estimates provided by the analysis. The member also pointed out that how the analysis is presented will matter, since it suggests that some regions might observe experience a decrease in SLK transplants, though that is not expected to occur. The member continued that it is easier to read a graph than any subsequent explanation.

The Workgroup agreed to move forward with the recommendation to expand the mandatory SLK allocation circle to 500 NM for SLK patients with a MELD of 29+, Status 1A, or Status 1B.

#### Next steps:

The Ad Hoc Multi-Organ Transplantation Committee will review the Workgroup's recommendations and determine whether to send a proposal out for public comment.

**Upcoming Meeting**

- TBD

## Attendance

- **Workgroup Members**
  - Lisa Stocks
  - Chris Curran
  - Arpita Basu
  - Dolamu Olaitan
  - Donna Smith
  - Jim Kim
  - Jim Sharrock
  - Rachel Engen
  - Chris Sonnenday
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Katherine Audette
- **UNOS Staff**
  - Erin Schnellinger
  - Kaitlin Swanner
  - Matt Cafarella
  - Meghan McDermott
  - Julia Foutz
  - Katrina Gauntt
  - Kayla Temple
  - Kelsi Lindbald
  - Kim Uccellini
  - Krissy Laurie
  - Lindsay Larkin
  - Ross Walton
  - Susan Tlusty
  - Paul Franklin