OPTN

Public Comment Proposal

Expand Required Simultaneous Liver-Kidney Allocation

OPTN Ad Hoc Multi-Organ Transplantation Committee

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Expand Required Simultaneous Liver-Kidney Allocation

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Sponsoring Committee: *Ad Hoc Multi-Organ Transplantation*
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Executive Summary

OPTN liver-kidney allocation policy requires organ procurement organizations (OPOs) to offer the kidney with the liver to candidates who are registered at a transplant program within specified distances from the donor hospital and who meet certain clinical criteria, including medical urgency for liver transplant and kidney dysfunction. Beyond the specified distance thresholds for required shares, the OPO may then either offer the kidney and liver to any liver-kidney candidates who meet the clinical criteria for kidney dysfunction, or offer the liver to liver-alone candidates and offer the kidney to kidney-alone candidates. As a result, there is variation in whether an OPO opts to allocate a kidney with a liver to candidates who meet the clinical criteria for both organs but fall outside the distance threshold for required shares.

The Ad Hoc Multi-Organ Transplantation Committee proposes expanding the distance threshold for required liver-kidney allocation. This change is expected to improve equity in access to simultaneous liver-kidney transplantation across the nation. Based on current OPO practice, this change is not expected to greatly increase liver-kidney transplants, and is not expected to have a large impact on access to kidney-alone or pancreas-kidney transplantation. However, this change would make it more likely that candidates requiring a simultaneous liver-kidney transplant receive offers for the organs they need. This proposal would also update liver-kidney policy so that the OPO may offer the liver and kidney in accordance with other multi-organ policies once the OPO completes all required liver-kidney offers. Finally, the proposal includes other non-substantive changes to liver-kidney policy for clarity and to further align liver-kidney policy with other multi-organ policies.

Purpose

The purpose of this proposal is to improve equity in access to simultaneous liver-kidney (SLK) transplantation by expanding the distance threshold at which an organ procurement organization (OPO) must offer a kidney along with a liver to candidates meeting clinical eligibility criteria. This proposal would also update liver-kidney policy so that the OPO may offer the liver and kidney in accordance with other multi-organ policies once the OPO completes all required liver-kidney offers. Finally, the proposal includes other non-substantive changes to liver-kidney policy for clarity and to further align liver-kidney policy with other multi-organ policies.

Background

OPTN policies have historically required OPOs to allocate multiple organs from the same donor to multi-organ candidates meeting certain criteria prior to allocating individual organs to single organ candidates. The intent of these policies is to promote access to transplant for candidates experiencing multi-organ failure, since it can be harder for candidates to find a good match with two or more organs from the same donor.[1] Additionally, receiving organs from the same donor instead of from different donors may reduce the level of the recipient's immune system response and lower the risk that their body will reject the organs.[2] However, given the scarcity of organs, allocating more than one organ to a single candidate must be weighed against the opportunity to allocate lifesaving organs to multiple potential transplant recipients. Accordingly, multi-organ policies limit when an OPO must offer more than one organ to the same candidate to ensure those candidates have medical urgency or clinical justification to receive both organs.

In 2017, the OPTN implemented policy for SLK allocation.[3] This policy was prompted by concerns about the increasing volume of SLK transplants following a shift in liver allocation policy that gave greater access for liver-kidney transplant offers to more medically urgent liver candidates.[4] The policy established medical eligibility criteria for SLK allocation, stating that the OPO must offer the kidney with the liver to candidates who met clinical criteria based on their kidney dysfunction as outlined in **Table 1.**[5]

[1] Donation rates vary by organ and are highest for kidneys, followed by liver, heart, lung, and pancreas, which means that some donors will not be able to donate all of the organs that a multi-organ candidate needs. See OPTN/SRTR 2020 Annual Data Report. Published 2022. Accessed December 2, 2022. http://srtr.transplant.hrsa.gov/annual_reports/Default.aspx. For donors that are able to donate multiple organs, there may be other organ-specific reasons why one of the organs would not be a good match for a certain multi-organ candidate, e.g., biopsy results unacceptable or organ anatomical damage or defect. See "Update to Refusal Codes," OPTN, Notice of Changes to OPTN Data Collection, accessed December 2, 2022, https://optn.transplant.hrsa.gov/media/4695/update_to_refusal_codes_june_2021_policy_notice.pdf.

[2] Receiving an organ transplant is a risk factor for sensitization. Candidates who are sensitized cannot accept donor organs with certain antigens due to the risk of morbidity and mortality. See Sarah Abbes, Ara Metjian, Alice Gray et al., "HLA sensitization in solid organ transplantation: a primer on terminology, testing, and clinical significance for the aphersis practitioner," *Therapeutic Apheresis and Dialysis* 21 no. 5 (2017): 441-450, DOI: 10.1111/1744-9987.12570.

[3] "Simultaneous liver-kidney allocation 2016," OPTN, accessed November 7, 2021, https://optn.transplant.hrsa.gov/governance/public-comment/simultaneous-liver-kidney-allocation-2016/.

[4] Mark I. Aeder, "Simultaneous Liver-Kidney Transplantation: Policy Update and the Challenges Ahead," *Current Transplantation Reports* 5 (2018): 130-138, https://doi.org/10.1007/s40472-018-0190-0.

[5] These medical eligibility criteria only apply to adult candidates. OPOs are required to allocate a liver and kidney to any pediatric candidates (under age 18 when registered on the liver waiting list) who are registered for both a liver and kidney.

Table 1: Medical Eligibility Criteria for Liver-Kidney Allocation

If the candidate's transplant nephrologist confirms a diagnosis of:	Then the transplant program must report to the OPTN and document in the candidate's medical record:
Chronic kidney disease (CKD) with a GFR less than or equal to 60 mL/min for greater than 90 consecutive days	At least *one* of the following: • That the candidate has begun regularly administered dialysis as an end-stage renal disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting. • At the time of registration on the kidney waiting list, that the candidate's most recent GFR or measured or estimated creatinine clearance (CrCl) is less than or equal to 30 mL/min. • On a date after registration on the kidney waiting list, that the candidate's GFR or measured or estimated CrCl is less than or equal to 30 mL/min.
Sustained acute kidney injury	At least *one* of the following, or a combination of *both* of the following, for the last 6 weeks: • That the candidate has been on dialysis at least once every 7 days. • That the candidate has a GFR or measured or estimated CrCl less than or equal to 25 mL/min at least once every 7 days. If the candidate's eligibility is not confirmed at least once every seven days for the last 6 weeks, the candidate is not eligible to receive a liver and a kidney from the same donor.
Metabolic disease	A diagnosis of at least *one* of the following: • Hyperoxaluria • Atypical hemolytic uremic syndrome (HUS) from mutations in factor H or factor I • Familial non-neuropathic systemic amyloidosis • Methylmalonic aciduria

In addition to establishing medical eligibility criteria for SLK transplant, the proposal also included geographic limitations for the allocation of SLK offers for OPOs. Specifically, the proposal required OPOs to allocate the kidney with the liver for all candidates in the same donation service area (DSA) as the donor hospital who met the medical eligibility criteria, and all candidates in the same OPTN Region[6] as the donor hospital who met the medical eligibility criteria and also had a MELD[7] or PELD[8] score of at least 35 or was assigned to Status 1A.[9,10]

[6] "Regions," OPTN, accessed December 5, 2022, https://optn.transplant.hrsa.gov/about/regions/.
[7] Model for End-stage Liver Disease.
[8] Pediatric End-stage Liver Disease
[9] "Simultaneous liver-kidney allocation 2016," OPTN, accessed November 7, 2021, https://optn.transplant.hrsa.gov/governance/public-comment/simultaneous-liver-kidney-allocation-2016/.
[10] Status 1A is reserved for the most medically urgent liver transplant candidates. These candidates have a life expectancy of less than 7 days. without transplant.

In 2018, the OPTN Board of Directors approved the Acuity Circles (AC) allocation policy for livers and intestines, which removed the use of DSAs and OPTN Regions from liver and intestine allocation.[11] As part of this proposal, SLK allocation was also changed to remove the use of DSAs and OPTN Regions.

The updated policy for SLK allocation maintained the same medical eligibility requirements as outlined in **Table 1** above but replaced the use of DSAs and OPTN Regions with 150 and 250 NM circles around the donor hospital, respectively. This policy, which remains in place today, states that an OPO must allocate the kidney with the liver to candidates meeting the medical eligibility criteria in **Table 1** and who are one of the following:

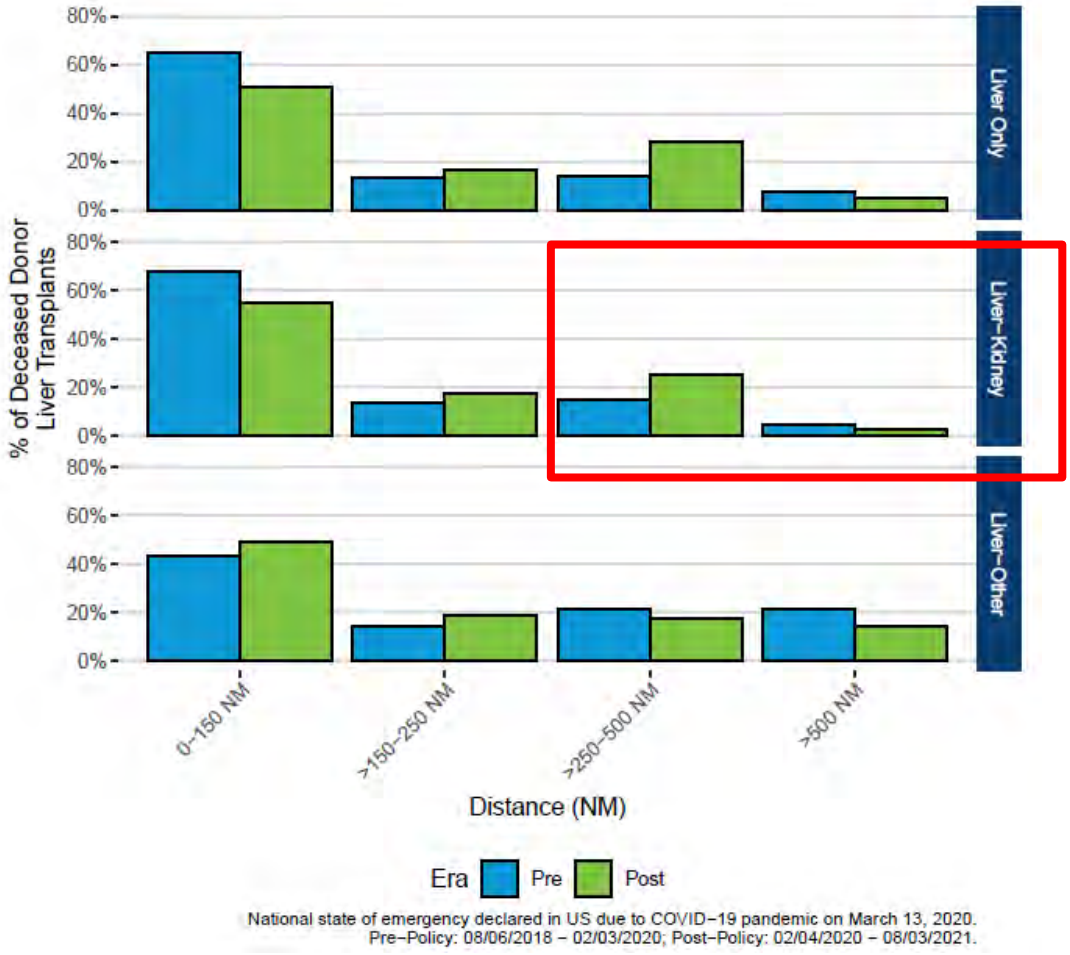
- Within 150 nautical miles of the donor hospital and have a MELD or PELD of 15 or higher
- Within 250 nautical miles of the donor hospital and have a MELD or PELD of at least 29
- Within 250 nautical miles of the donor hospital and status 1A or 1B

The OPTN Liver and Intestinal Organ Transplantation Committee recommended the 150 and 250 NM circles in consultation with the OPTN Kidney Transplantation Committee in an attempt to maintain similar geographic restrictions that existed in the previous SLK policy.[12]

If the SLK offer is not accepted for candidates meeting the criteria described above, the OPO may continue to offer the kidney along with the liver to candidates who meet the clinical criteria in **Table 1** who are registered at transplant programs beyond 250 NM from the donor hospital, or the OPO may choose to allocate the liver to liver-alone candidates and the kidney to kidney-alone candidates. OPTN data has shown that OPOs sometimes offer the kidney along with the liver between 250 to 500 NM, as **Figure 1** shows that SLK transplants occur within this range. However, this decision is left to the discretion of the individual OPO, which could preclude an SLK candidate who meets the clinical eligibility criteria from accessing the required organs in a timely and equitable fashion.

[11] Liver and Intestine Distribution Using Distance from Donor Hospital," OPTN, accessed November 16, 2022, https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf
[12] Ibid.

Figure 1. Deceased Donor Liver Transplants by Multi-Organ Type, Classification Distance, and Era



Since development of the SLK allocation policy, the OPTN has developed policies for other multi-organ combinations to provide equity in access to transplants between multi-organ and single-organ candidates. In February 2022, the OPTN implemented updates to multi-organ allocation that expanded required shares for simultaneous heart-kidney (SHK) and simultaneous lung-kidney (SLuK) allocation out to 500 NM for candidates who met medical urgency criteria for heart, lung, or heart-lung.[13] The 500 NM distance was selected to align with the first four classifications in heart allocation policy, which extend out to 500 NM.[14] In June 2022, the OPTN Board of Directors approved further changes to this policy that added additional medical eligibility criteria related to kidney dysfunction, modeled off the SLK eligibility criteria outlined in **Table 1**.[15] These changes are slated for implementation in 2023. Separately, the OPTN Board of Directors approved updates to lung-kidney policy to replace the 500 NM distance threshold with a composite allocation score threshold as part of the continuous distribution of lungs

[13] "Clarify Multi-Organ Allocation Policy," OPTN, Policy Notice, accessed November 20, 2022, https://optn.transplant.hrsa.gov/media/4698/clarify_multi-organ_june_2021_policy_notice.pdf.
[14] "Clarify Multi-Organ Allocation Policy," OPTN, Briefing Paper, accessed December 5, 2022, https://optn.transplant.hrsa.gov/media/4634/briefing-paper_june-2021_clarify-multi-organ-policy_draft.pdf.
[15] "Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation," OPTN, Policy Notice, accessed November 16, 2022, https://optn.transplant.hrsa.gov/media/erucde2m/policy-notice_est-elgblty-crit-and-safety-for-hrt-kid-and-lung-kid-alloc_mot.pdf.

allocation framework.[16,17] A comparison of the approved policies for SLK, SHK, and SLuK policies are summarized in **Table 2**.

Table 2: Comparison of Approved Policies for Simultaneous Liver-Kidney, Heart-Kidney, and Lung-Kidney Allocation

Policy	Liver-Kidney	Heart-Kidney	Lung-Kidney
Primary organ criteria (adult)	150 NM: MELD/PELD 15+ 250 NM: MELD/PELD 29+ 250 NM: Status 1A or 1B	500 NM: Status 1, 2, 3, 4, or 5[18]	Composite Allocation Score 25+ (accounts for distance)[19]
Kidney criteria[20]	Chronic kidney disease Sustained acute kidney injury Metabolic disease	Chronic kidney disease Sustained acute kidney injury	Chronic kidney disease Sustained acute kidney injury
Pediatric candidates	Unrestricted	Within 500 NM	Unrestricted

Following the approval of the policies for heart-kidney and lung-kidney, OPTN members expressed concern that the distance for SLK required shares only extend out to 250 NM, whereas required shares for SHK extend out to 500 NM. While OPOs do sometimes offer the kidney with the liver beyond 250 NM, as shown in **Figure 1** above, sometimes they do not. Members of the OPTN Liver and Intestinal Organ Transplantation Committee provided anecdotal evidence of instances where OPOs have allocated a liver-alone but not an SLK combination to candidates meeting the MELD threshold and kidney dysfunction criteria in OPTN policy, but who are registered at a transplant hospital that is farther than 250 NM from the donor hospital.

The Liver and Intestinal Organ Transplantation Committee proposed a project to align the distance threshold for required SLK shares with the 500 NM distance threshold in place for required SHK shares. The Policy Oversight Committee directed the Ad Hoc Multi-Organ Transplantation (MOT) Committee (Committee) to sponsor this project.[21] The Committee established the Simultaneous Liver-Kidney (SLK) Workgroup (Workgroup) to request and review data, and to develop recommendations for the Committee on this topic. The Workgroup included members from the MOT, Liver, Kidney, OPO, and Pediatric Committees, including an MOT recipient. The Committee reviewed the Workgroup's recommendations and developed this proposal.

Overview of Proposal

The Committee proposes expanding the geographic threshold for required simultaneous liver-kidney offers from 250 NM to 500 NM for candidates with MELD of 29 or greater and for candidates assigned to liver Status 1A or 1B. The Committee also proposes updating the policy so that the OPO may offer the

[16] "Establish Continuous Distribution of Lungs," OPTN, Policy Notice, accessed December 5, 2022, https://optn.transplant.hrsa.gov/media/b13dlep2/policy-notice_lung_continuous-distribution.pdf.
[17] "Update Multi-Organ Allocation for Continuous Distribution of Lungs," OPTN, accessed December 5, 2022, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/update-multi-organ-allocation-for-continuous-distribution-of-lungs/.
[18] "Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation," OPTN, Policy Notice, accessed November 16, 2022, https://optn.transplant.hrsa.gov/media/erucde2m/policy-notice_est-elgblty-crit-and-safety-for-hrt-kid-and-lung-kid-alloc_mot.pdf.
[19] "Update Multi-Organ Allocation for Continuous Distribution of Lungs," OPTN, accessed December 5, 2022, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/update-multi-organ-allocation-for-continuous-distribution-of-lungs/.
[20] The criteria for the chronic kidney disease and sustained acute kidney injury diagnoses are consistent across the liver-kidney, heart-kidney, and lung-kidney policies. These criteria are listed in Table 1 of this proposal.
[21] Policy Oversight Committee, OPTN, Meeting Summary for September 12, 2022, accessed November 20, 2022, https://optn.transplant.hrsa.gov/media/q5qp3wj5/20220912_optn_poc_meeting_summary.pdf.

liver and kidney in accordance with other multi-organ policies once the OPO completes all required SLK offers. Finally, the Committee proposes a number of non-substantive changes to align SLK policy with other multi-organ policies and to improve clarity on an OPO's obligation under the policy.

Expanding SLK Required Shares to 500 NM

This proposal would require an OPO to offer the kidney along with the liver to qualifying candidates within 500 NM of the donor hospital, rather than within 250 NM as required by current policy. The proposed changes relative to current SLK policy are summarized in **Table 3**. This proposal would not change SLK policy for pediatric candidates. Accordingly, OPOs must still offer the kidney along with the liver to candidates who were less than 18 years old when registered on the liver waiting list and are also registered for a kidney, regardless of their distance from the donor hospital or whether they meet the criteria in **Table 1**.

Table 3: Comparison of Current and Proposed SLK Policies

Current Policy	Proposed Policy
Kidney must be offered with the liver if candidate was age 18 or older when registered on the liver list, meets the criteria in **Table 1**, and is: • Within 150 NM, MELD of 15 or greater • Within 250 NM, MELD of 29 or greater • Within 250 NM, Status 1A or 1B	Kidney must be offered with the liver if candidate was age 18 or older when registered on the liver list, meets the criteria in **Table 1**, and is: • Within 150 NM, MELD of 15 or greater • Within **500 NM**, MELD of 29 or greater • Within **500 NM**, Status 1A or 1B

The Committee is proposing this change to improve equity in access to SLK transplants by:

- Reducing variability in OPO practice, thereby making it more likely that candidates with the same medical criteria will be offered both the liver and the kidney
- Aligning the distance threshold for required shares in SLK policy with SHK policy, thereby promoting more equal access to transplant between SLK and SHK candidates

Based on data reviewed by the Committee, the Committee does not anticipate this proposal to have a large impact on access to kidney-alone or pancreas-kidney transplantation, as described below.

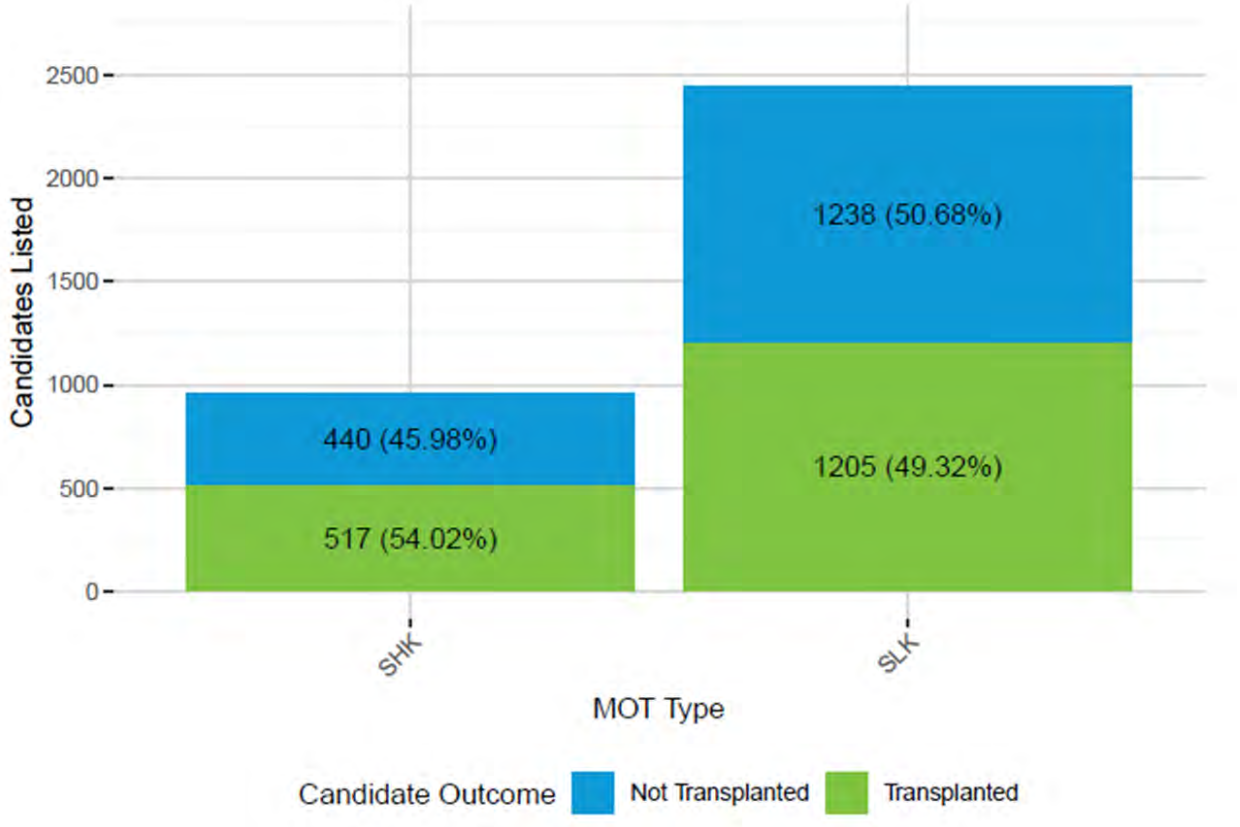
Reducing Variability in OPO Practice

As noted previously, the current SLK allocation policy allows OPOs to decide whether to continue to offer the kidney with the liver beyond 250 NM, or to allocate the kidney to kidney-alone candidates and the liver to liver-alone candidates. The Committee acknowledged that leaving this discretion to OPOs has the potential to harm candidates who meet the clinical criteria for an SLK transplant but fall outside the 250 NM circle. By expanding the required allocation threshold to 500 NM, it will be less likely that OPOs are put in a position to decide between allocating an SLK combination to SLK candidates outside 250 NM or allocating the liver and kidney to other candidates. The Committee agreed that, to a certain extent, the distance between the transplant program and donor hospital should not matter for candidates who otherwise meet the medical eligibility criteria for SLK transplant. While the Committee ultimately supports replacing the distance threshold with a more suitable threshold in a continuous distribution framework, similar to the composite allocation score threshold approved for lung-kidney allocation, the Committee notes that continuous distribution of livers and intestines would not be implemented for a few more years. Accordingly, the Committee determined that it is appropriate to change the required shares threshold to 500 NM in the interim to more quickly address the variability in permissive SLK offers.

Aligning SLK Policy with SHK Policy

As indicated above in **Table 2**, SHK policy requires the OPO to offer the kidney with the heart to eligible candidates within 500 NM of the donor hospital, whereas SLK policy only requires the OPO to offer the kidney with the liver to eligible candidates within a maximum range of 250 NM from the donor hospital. The OPTN has previously recommended that multi-organ polices should be consistent across organ combinations unless there is an ethical justification for a different system.[22] It is possible that different distance thresholds for SHK and SLK policies could yield similar access to transplant for SHK and SLK candidates, given that there are more donors with suitable livers for transplant than hearts,[23] and hearts generally cannot withstand as much cold preservation time as livers.[24] However, the Committee reviewed data indicating that SHK candidates have slightly more access to transplant than SLK candidates, as measured by the proportion of candidates transplanted; the Kidney Donor Profile Index (KDPI) of kidneys used in SHK transplant relative to SLK transplant; the average removals-to-waiting ratio; and the average transplant-to-waiting ratio, as shown in **Figures 2**, **3**, **4**, and **5**, respectively.

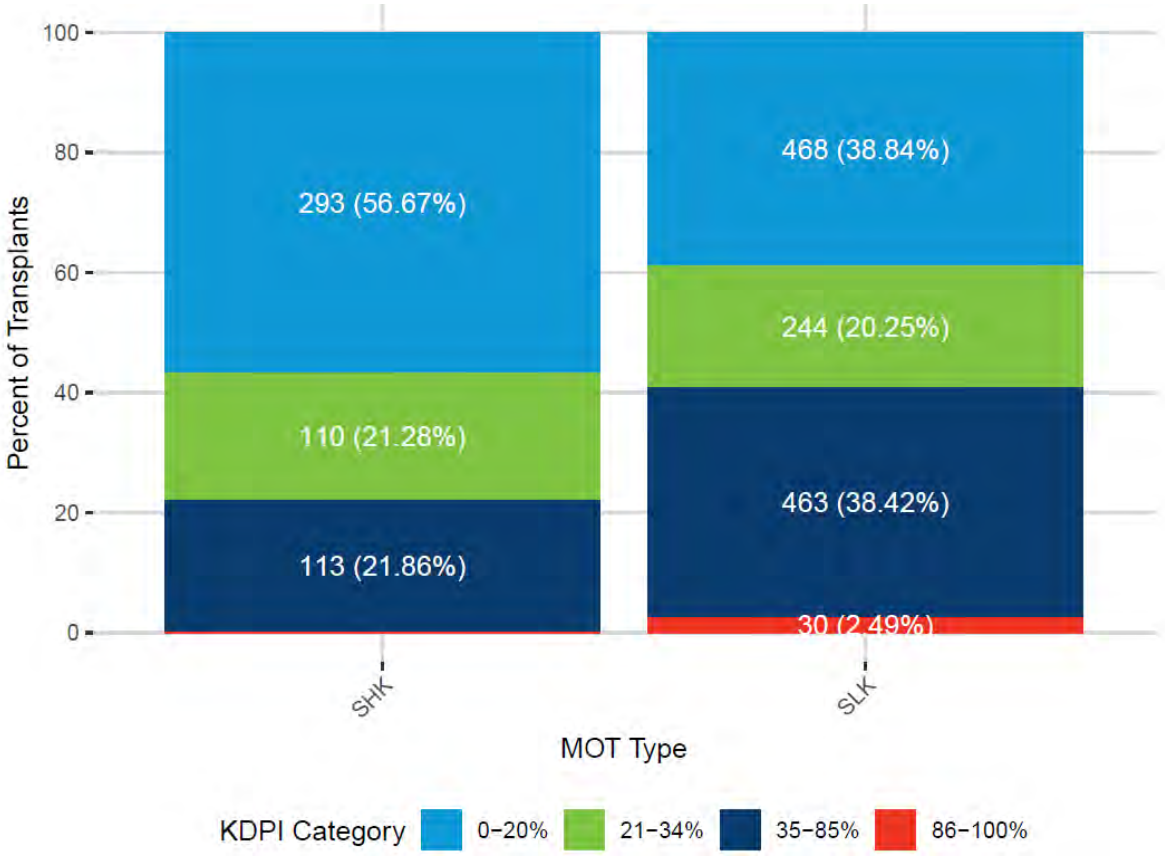
Figure 2: SHK and SLK Transplants between February 4, 2020 and February 3, 2022 based on Candidates Listed in that Timeframe[25]



[22] "Ethical Implications of Multi-Organ Transplants," OPTN, White Paper, accessed November 20, 2022, https://optn.transplant.hrsa.gov/media/2989/ethics_boardreport_201906.pdf.
[23] OPTN/SRTR 2020 Annual Data Report. Published 2022. Accessed December 2, 2022. http://srtr.transplant.hrsa.gov/annual_reports/Default.aspx.
[24] "How organ allocation works," OPTN, accessed December 5, 2022, https://optn.transplant.hrsa.gov/patients/about-transplantation/how-organ-allocation-works/.
[25] Katrina Gauntt and Erin Schnellinger, "Data Request – SLK Transplants," OPTN, Descriptive Data Request for the Ad Hoc Multi-Organ Transplantation Committee Simultaneous Liver-Kidney Workgroup, November 7, 2022.

As shown in **Figure 2**, 54.02% of heart-kidney candidates received SHK transplants between February 4, 2020, and February 3, 2022, whereas 49.32% of liver-kidney candidates received SLK transplants in that timeframe.

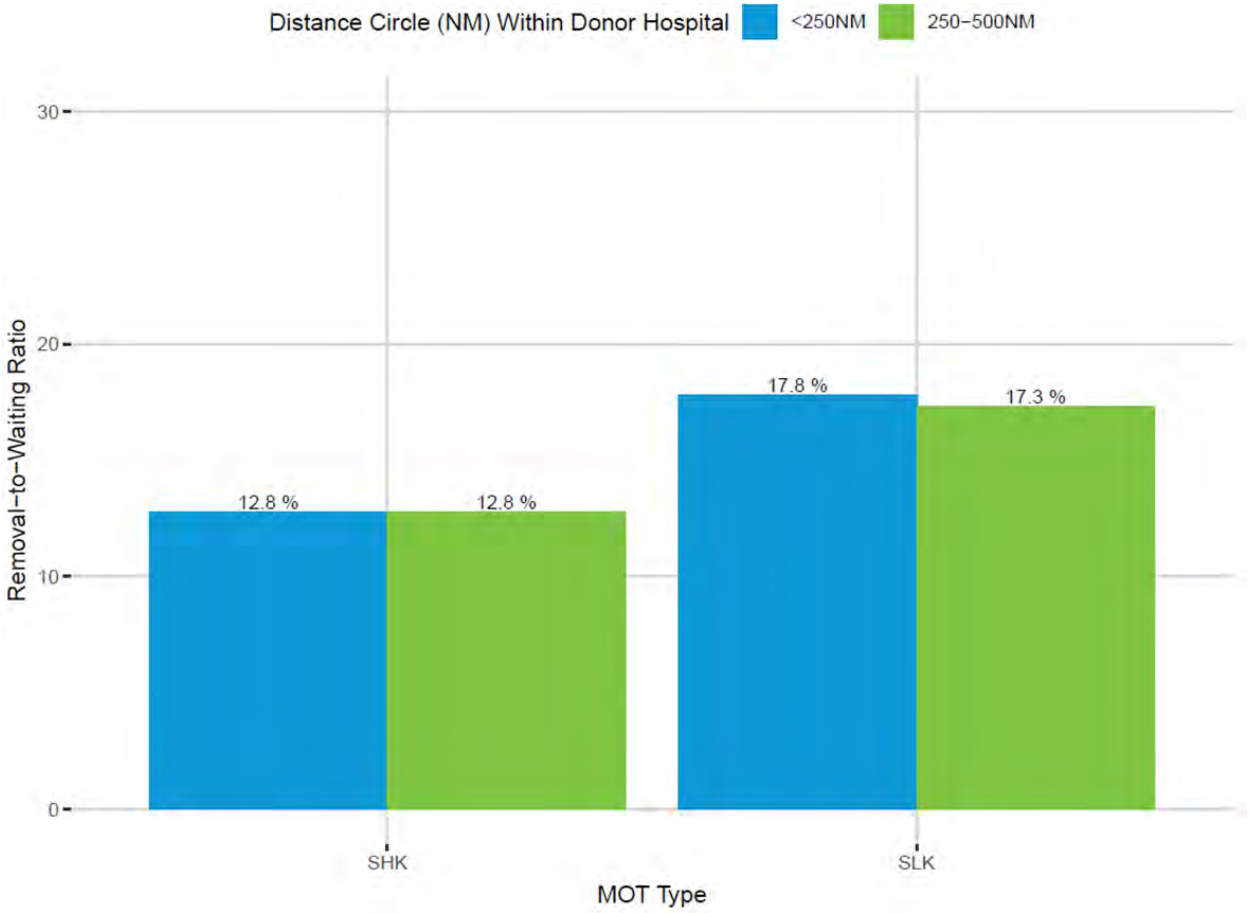
Figure 3. SHK and SLK Transplants by KDPI between February 4, 2020 and February 3, 2022[26]



SHK recipients also tended to receive kidneys with a lower KDPI, as shown in **Figure 3**. KDPI estimates how long a kidney from a deceased donor may function after transplant, with a lower KDPI indicating that a kidney is expected to function longer. The majority of SHK recipients (56.67%) received a kidney with a KDPI of 20% or less, whereas only 38.84% of SLK recipients received a kidney with a KDPI of 20% or less.

[26] Ibid.

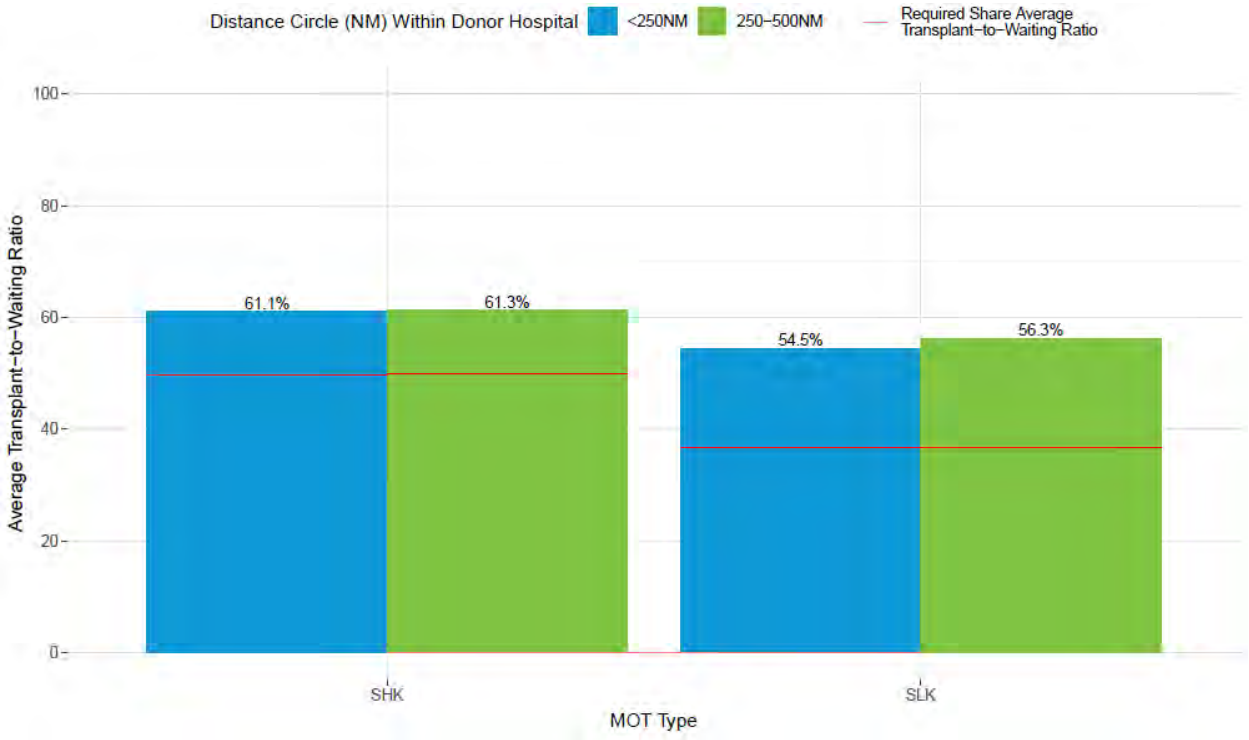
Figure 4. The Ratio of the Average Number of Removals Due to Death/Too Sick to OPTN Waiting List Additions by Distance Circles from the Donor Hospital for SHK and SLK[27]



The average waiting-to-removals ratio was lower for SHK candidates than SLK candidates, both within 250 NM and between 250 to 500 NM from the donor hospital, as shown in **Figure 4**. This means that compared to SLK, there were fewer SHK candidates removed from the waiting list due to death or because they were too sick for transplant relative to the number of SHK candidates waiting for transplant. This may reflect a tendency for OPOs to place thoracic organs (hearts and lungs) before abdominal organs, since thoracic organs cannot withstand as much preservation time as abdominal organs.[28] Accordingly, OPOs may be more likely to offer a kidney along with a heart or lung before the kidney can be offered along with a liver.

[27] Ibid.
[28] "How organ allocation works," OPTN, accessed December 5, 2022, https://optn.transplant.hrsa.gov/patients/about-transplantation/how-organ-allocation-works/.

Figure 5. The Average Transplant-to-Waiting Ratio by Distance Circles from Donor Hospital for SHK and SLK[29]



Finally, **Figure 5** shows that SHK candidates had a higher transplant-to-waiting ratio than SLK candidates. The transplant-to-waiting ratio was calculated by dividing the average number of transplants by the average number of candidates waiting, both within 250 NM from the donor hospital and between 250-500 NM from the donor hospital. This means that on average, more SHK candidates received transplants relative to the number of candidates waiting compared to SLK candidates.

The Committee is not aware of a clinical reason for the distance thresholds to differ between the organs, since it is feasible for hearts, livers, and kidneys to travel out to 500 NM and beyond.[30,31,32] Additionally, the clinical criteria for kidney dysfunction based on a diagnosis of chronic kidney disease or sustained acute kidney injury are the same for both SLK and SHK candidates. Candidates meeting these criteria gain a survival advantage when receiving the kidney along with the liver or heart, relative to liver-alone

[29] Ibid.

[30] Erin Schnellinger, Keighly Bradbrook, and Kelsi Linblad, "Three-Year Monitoring of Heart Allocation Proposal to Modify the Heart Allocation System," OPTN, Descriptive Data Request prepared for the Heart Transplantation Committee, September 12, 2022, accessed December 13, 2022, https://optn.transplant.hrsa.gov/media/hx1pr13a/data_report_heart_committee_3yr_rpt1_508_compliant.pdf. See Figure 21, "Distance Traveled at Transplant by Era."

[31] Samantha Weiss and Julia Foutz, "Two Year Monitoring Report of Liver and Intestine Acuity Circle Allocation: Removal of DSA and Region as Units of Allocation," OPTN, Descriptive Data Request prepared for the Liver & Intestinal Transplantation Committee, August 5, 2022, accessed December 13, 2022, https://optn.transplant.hrsa.gov/media/k5yi4ivl/data_report_liver_full_2yrallocation_20220805_final_508_compliant.pdf. See Figure 36, "Adult Deceased Donor Liver-Alone Transplants by Classification Distance and Era."

[32] Amanda Robinson, Sarah Booker, and Katrina Gauntt, "Eliminate Use of DSA and Region from Kidney Allocation One-Year Post-Implementation Monitoring Report," OPTN, Descriptive Data Request for the Kidney Transplantation Committee, July 1, 2022, accessed December 13, 2022, https://optn.transplant.hrsa.gov/media/p2oc3ada/data_report_kidney_full_20220624_1.pdf. See Figure 6, "Distribution of Distance from Donor Hospital for Deceased Donor Kidney Transplants."

and heart-alone recipients with pre-transplant renal dysfunction.[33,34] Accordingly, the Committee determined that it would be appropriate to align the distance threshold for SHK and SLK allocation, thereby balancing equity in access to transplant between these two groups of candidates.

Impact on Kidney-Alone and Pancreas-Kidney Candidates

Throughout the development of this proposal, the Committee's primary concern with expanding required SLK allocation out to 500 NM was the potential impact on kidney-alone and pancreas-kidney candidates. With a limited supply of available organs, the concern was that expanding SLK allocation would reduce the number of available deceased donor organs for kidney-alone and pancreas-kidney candidates.

As shown above in **Figure 2**, there were 1,205 SLK transplants between February 4, 2020 and February 3, 2022, more than double the 517 SHK transplants in the same period. Accordingly, the concern raised, particularly by members of the kidney and pancreas communities, was that if SLK offers were required out to 500 NM, then the number of SLK transplants would increase, and kidney-alone and pancreas-kidney candidates would lose access to the kidney offers they would have otherwise received. Members were particularly concerned about the potential impact on pediatric and highly sensitized kidney candidates.

Accordingly, the Workgroup submitted a data request to quantify the extent of variation in donor availability for SLK transplants within 250 NM of donor hospitals versus 250-500 NM from donor hospitals. The purpose of this data request was to estimate how the overall volume of SLK transplants might change if required SLK offers were extended out to 500 NM. The analysis indicated that the predicted number of SLK transplants between 250 and 500 NM of each donor hospital is not expected to increase substantially as a result of requiring SLK allocation out to 500 NM, since some OPOs are already choosing to allocate the liver with the kidney beyond 250 NM. Therefore, this proposal is not anticipated to have a large impact on access to transplant for kidney-alone and pancreas-kidney candidates, but it will improve access to transplant for liver-kidney candidates falling within 250-500 NM of donor hospitals who would not otherwise receive those offers.

The analysis compared the average number of SLK transplants that occurred within 250 to 500 NM of each donor hospital to the anticipated number of SLK transplants that would occur if the distance for required shares was expanded to 500 NM. To calculate the estimated average number of additional transplants within 250-500 NM, the OPTN first calculated the transplant-to-waiting ratio for SLK candidates within 250 NM of each donor hospital using historic data. Assuming this transplant-to-waiting ratio would remain consistent for candidates between 250 and 500 NM, the average number of transplants that would be expected to occur between 250 and 500 NM was then calculated as outlined in **Figure 6**.

[33] Pratima Sharma, Xu Shu, Douglas E. Schaubel, et al., "Propensity Score-Based Survival Benefit of Simultaneous Liver-Kidney Transplant Over Liver Transplant Alone for Recipients with Pretransplant Renal Dysfunction," *Liver Transplantation* 22 (2016): 71-79, DOI 10.1002/lt.24189.
[34] Tara Karamlou, Karl Welke, D. Michal McMullan, et al., "Combined heart-kidney transplant improves post-transplant survival compared with isolated heart transplant in recipients with reduced glomerular filtration rate: Analysis of 593 combined heart-kidney transplants from the United Network Organ Sharing Database," Cardiothoracic Transplantation 147, no. 1 (January 2014): 456-461, https://doi.org/10.1016/j.jtcvs.2013.09.017.

Figure 6: Average Number of Transplants Calculation

$$\frac{\text{Average \# of Transplants}}{\text{Average \# of Candidates Waiting}}_{<250\text{ NM}} = \frac{\text{Average \# of Transplants}}{\text{Average \# of Candidates Waiting}}_{250-500\text{ NM}}$$

The estimated average number of additional transplants within 250-500 NM of the donor hospital was -7.4, as shown in **Table 4**.

Table 4: Estimated Number of SLK Transplants at 250-500 NM based on the Transplant-to-Waiting Ratio Seen for SLK at 250 NM

250 NM Transplant-to-Waiting Ratio	Waitlist Additions Averages Within 250-500NM of the Donor Hospitals	Estimated Average Number of Transplants within 250-500NM	Actual Transplants within 250-500NM	Estimated Average Additional Transplants within 250-500NM of a Donor Hospital
0.545	397.2	216.4	223.8	-7.4

To arrive at this estimate, the estimated average number of transplants within 250-500 NM, which was 216.4, was determined by multiplying the 250 NM transplant-to-waiting ratio (0.545) by the waitlist additions averages within 250-500 NM of the donor hospitals (397.2). The actual number of transplants within 250-500 NM was 223.8, which is 7.4 more transplants than the estimated average number of transplants within 250-500 NM.

The Committee does not expect a reduction in SLK transplants if this proposal were to be implemented, and interprets this analysis to indicate that the expected increase in SLK transplants would be modest. Since OPOs are allowed to allocate SLK combinations between 250-500 NM under current policy, this analysis suggests that most OPOs are choosing to do so, rather than allocating the liver to liver-alone candidates and the kidney to kidney-alone candidates. Accordingly, the Committee expects that expanding required SLK shares to 500 NM would not have large impact on the overall number of SLK transplants, and therefore is unlikely to have a significant impact on access to transplant for the kidney-alone and pancreas-kidney populations. Some members of the Committee noted that if there is not expected to be a significant increase in SLK transplants and most OPOs are already allocating SLK combinations beyond 250 NM, then expanding the distance threshold for required shares to 500 NM may not be needed. However, there are still instances of OPOs choosing not to allocate an SLK to candidates meeting the medical criteria, so the Committee agreed that the policy should be expanded.

The Committee reviewed the expected change in SLK transplants by OPTN Region, using the calculation shown in **Figure 6**. The analysis indicated that SLK transplants may increase in Regions 3, 6, 7, 8, and 10 by a range of 4-17 transplants over two years. This is not a forecast, but an estimate based on counterfactual averages of the change in SLK transplant volume that could occur when expanding required shares out to 500 NM. Regions 1, 2, 4, 5, 9, and 11 are not expected to see increases in SLK transplants, which suggests that OPOs in these regions are already allocating the liver with the kidney beyond 250 NM more often than would be expected by the average transplant-to-waiting ratio.

Permitted Shares Following Completion of Required Shares

Current SLK policy states that after the OPO has offered the kidney with the liver to all candidates who meet the criteria for required shares, then the OPO may do either of the following:

- Offer the kidney and liver to any candidate who meets eligibility criteria according to **Table 1**
- Offer the liver to liver-alone candidates and offer the kidney to kidney-alone candidates

As written, the policy does not give the OPO the option to offer the liver to other liver multi-organ candidates, like heart-liver or lung-liver candidates. This may reflect that donor heart and lungs are often placed first, due to their ischemic time restrictions. However, a situation could arise in which a heart is turned down later in the allocation process, once an OPO has completed all required liver-kidney offers. If the next candidate on the heart match run is a heart-liver candidate, the Committee agreed that the OPO should then offer the liver along with the heart in accordance with *Policy 5.10.G: Allocation of Heart-Liver and Lung-Liver*. Accordingly, the Committee proposes broadening the SLK policy language to allow the OPO to offer the liver in accordance with any other allocation policy involving a liver, rather than being restricted to offering the liver to a liver-alone candidate. This would also allow the OPO to offer the liver to multivisceral (liver-intestine or liver-intestine-pancreas) candidates following completion of required liver-kidney offers.

The policy also does not give the OPO the option to offer the kidney to other kidney multi-organ candidates, like a pancreas-kidney candidate. This may reflect an intent to balance access to transplant for kidney-alone candidates by requiring the OPO to offer the kidney to kidney-alone candidates rather than other kidney multi-organ candidates after completing required SLK shares. However, similar to the example above, a situation may arise in which a qualifying heart-kidney, lung-kidney, or pancreas-kidney candidate is next on the respective match run after the OPO has completed required SLK offers, and the Committee holds that the OPO should be able to offer the kidney in accordance with the policies for these other organ combinations. The Committee recognizes that several OPO members have requested additional direction on how to handle multi-organ allocation and has a related concept paper out for public comment this cycle entitled *Identify Priority Shares in Kidney Multi-Organ Allocation*.[35]

Non-substantive Policy Changes

The Committee proposes several modifications to SLK policy to improve clarity and better align the policy with other multi-organ policies. These changes are not intended to modify the OPO's obligation under the policy. The changes would:

- Clarify that mentions of MELD within the policy refer to a candidate's allocation MELD score
- Align the language about what the OPO must do with the language used in the heart-kidney, lung-kidney, heart-liver, and lung-liver policies
- Remove references to PELD scores, since the OPO must offer the kidney with the liver to candidates who were less than 18 years old when registered on the liver waiting list regardless of their PELD score or distance from the donor hospital, as long as they are also registered for a kidney
- Move the requirement to offer the kidney with the liver to candidates who were less than 18 years old when registered on the liver waiting list up in the policy, so that it is clear that pediatric candidates do not need to meet the eligibility criteria, and remove the existing sections of policy that make this distinction

[35] "Public comment," OPTN, accessed January 19, 2022, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/.

NOTA and Final Rule Analysis

The Committee submits this proposal for consideration under the authority of the National Organ Transplant Act of 1984 (NOTA) and the OPTN Final Rule. NOTA requires the OPTN to "establish…medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria."[36] The OPTN Final Rule states the OPTN "shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[37] This project impacts allocation as it would require the OPO to offer a kidney with a liver at longer distances than are currently required by policy, and would give OPOs more flexibility in how to offer the liver and the kidney following completion of required SLK offers.

The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed "in accordance with §121.8," which requires that allocation policies "(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;…(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section."[38] This proposal:

- **Is based on sound medical judgment:**[39] The Committee proposes these changes based on the medical judgment of transplant surgeons, transplant physicians, and members of fourteen stakeholder committees involved in the development of this proposal after reviewing OPTN data and analysis that estimated the potential impact of this proposal on SLK transplant volume.[40]
- **Seeks to achieve the best use of donated organs:**[41] This proposal does not change the medical eligibility criteria for required SLK offers, which were implemented to help ensure that a kidney is offered along with a liver only when the candidate is not expected to regain kidney function following liver transplant.[42] The medical eligibility criteria were also established based on evidence that receiving a kidney along with a liver provides a survival advantage to liver candidates with pre-transplant renal failure.[43,44] This proposal would ensure that candidates who are registered within 500 NM of the donor hospital and who meet the eligibility criteria to be offered a kidney along with the liver will be eligible to receive those organ offers.
- **Is designed to…promote patient access to transplantation**[45] **by** giving similarly situated liver-kidney candidates equitable opportunities to receive an organ offer, whether they are within 250 NM of the donor hospital or between 250-500 NM from the donor hospital. This change is intended to eliminate the current variation in whether or not candidates who meet the medical

[36] 42 USC §274(b)(2)(B).
[37] 42 CFR §121.4(a)(1).
[38] 42 CFR §121.8(a).
[39] 42 CFR §121.8(a)(1).
[40] Katrina Gauntt and Erin Schnellinger, "Data Request – SLK Transplants," OPTN, Descriptive Data Request for the Ad Hoc Multi-Organ Transplantation Committee Simultaneous Liver-Kidney Workgroup, November 7, 2022.
[41] 42 CFR §121.8(a)(2).
[42] "Simultaneous Liver Kidney (SLK) Allocation," OPTN, Briefing Paper, accessed November 20, 2022, https://optn.transplant.hrsa.gov/media/1871/kidney_briefingpaper_slk_201606.pdf.
[43] Ibid.
[44] Sharma et al., "Propensity Score-Based Survival Benefit," 77.
[45] Id.

eligibility criteria for SLK offers but are located between 250-500 NM from the donor hospital receive these organ offers. This proposal would also improve equity in access to transplant for liver-kidney candidates relative to heart-kidney candidates, in alignment with an OPTN recommendation that multi-organ polices should be consistent across organ combinations unless there is an ethical justification for a different system.[46]

- **Promotes the efficient management of organ placement[47] by** providing clear rules for when the kidney must be offered along with the liver, thereby reducing the frequency with which an OPO must decide whether to make a permissive SLK offer or offer the kidney and liver separately. This proposal more clearly establishes the flexibility OPOs have to offer the liver and the kidney following completion of the required shares, including allowing the organs to be placed as multi-organ combinations as appropriate.
- **Is not based on the candidate's place of residence or place of listing, except to the extent required to** promote patient access to transplantation and to promote efficient management of organ placement.[48] The best use of organs, avoiding unnecessary organ loss, and promoting the efficient management of organ placement may provide justification for constraining geographic distribution of organs due to the impact on ischemic time, travel logistics, utilization and outcomes. While this proposal would expand the existing geographic threshold for required SLK offers, it does not remove the geographic threshold completely because it could result in a more substantial increase in SLK transplant volume and negatively impact pancreas-kidney and kidney-alone transplant volume. This limit on required shares also promotes efficient organ placement by not requiring OPOs to offer organs at distances at which they are unlikely to be accepted. The Committee expects that the geographic threshold will be replaced with an updated threshold with less reliance on distance in a future proposal for continuous distribution of livers and intestines.

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient,[49] and it is specific to a combination of organ types, in this case liver-kidney.[50]

Although the proposal outlined in this briefing paper addresses certain aspects of the Final Rule listed above, the Committee does not expect impacts on the following aspects of the Final Rule:

- Is designed to avoid wasting organs[51]
- Is designed to avoid futile transplants[52]

Transition Plan

The Final Rule also requires the OPTN to "consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies" whenever organ allocation policies are revised.[53] The Committee recommended providing education to OPOs prior to implementation of the policy but determined that no transition plan is needed for transplant candidates as these policy changes would improve equity in access to transplant for SLK

[46] "Ethical Implications of Multi-Organ Transplants," OPTN, White Paper, accessed November 20, 2022, https://optn.transplant.hrsa.gov/media/2989/ethics_boardreport_201906.pdf.
[47] Id.
[48] 42 CFR §121.8(a)(8)
[49] 42 CFR §121.8(a)(3).
[50] 42 CFR §121.8(a)(4).
[51] 42 CFR §121.8(a)(5).
[52] Id.
[53] 42 CFR § 121.8(d).

candidates but is not expected to significantly reduce access to transplant to kidney-alone or pancreas-kidney candidates.

Implementation Considerations

This proposal is expected to affect the operations of OPOs, transplant hospitals, and the OPTN, but is not expected to affect the operations of histocompatibility laboratories.

Member and OPTN Operations

Operations affecting Organ Procurement Organizations

OPOs would need to train staff on the update to SLK allocation policy. Required shares would be indicated on the match run.

Operations affecting Transplant Hospitals

Transplant hospitals would not need to take any action to implement this proposal, but may see increased access to SLK transplant for their liver-kidney candidates, particularly in Regions 3, 6, 7, 8, and 10.

Operations affecting the OPTN

The OPTN is working sequentially to consider continuous distribution allocation systems for deceased donor organs.[54] The OPTN Liver and Intestinal Organ Transplantation Committee is currently working on a proposal to transition the liver and intestine allocation systems to a continuous distribution framework.[55] If approved, the OPTN expects to implement the expanded distance threshold for required SLK offers prior to implementation of continuous distribution of livers and intestines. The OPTN Liver and Intestinal Organ Transplantation Committee would consider how to replace this distance threshold for required shares as part of the continuous distribution proposal, but determined that it was important to address the inequities in SLK transplant access at this time rather than waiting until continuous distribution is implemented for livers and intestines.

The OPTN would need to update the liver match run in the OPTN Donor Data and Matching System to reflect the expanded distance for required SLK offers. The OPTN would also need to provide education and communications on the changes for members.

Potential Impact on Select Patient Populations

This proposal is expected to improve access to transplantation for liver-kidney candidates who meet medical eligibility criteria for required offers. Under the current policy, there are liver-kidney candidates who meet both the liver and kidney medical criteria for simultaneous liver-kidney offers but fall outside the 250 NM circle for required shares, and are not receiving offers for both organs from the same donor. This policy change would require the OPO to offer the kidney with the liver to qualifying candidates out to 500 NM. Since some OPOs already offer the kidney with the liver to qualifying candidates between 250-500 NM, this proposal is not expected to have a significant impact on pancreas-kidney or kidney-alone candidates.

[54] "Continuous Distribution," OPTN, accessed January 24, 2022, https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/.
[55] "Continuous Distribution of Livers and Intestines Concept Paper," OPTN, accessed November 20, 2022, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/continuous-distribution-of-livers-and-intestines-concept-paper/.

Projected Fiscal Impact

This proposal is expected to have a fiscal impact on organ procurement organizations, transplant hospitals, and the OPTN, but is not expected to have an impact on histocompatibility laboratories.

Projected Impact on Organ Procurement Organizations

Broader sharing of organs would result in increased cost of travel for OPOs. The proposed changes should reduce the number of times OPOs will need to decide between SLK and single-organ candidates.

Projected Impact on Transplant Hospitals

The proposal is not expected to have a substantial fiscal impact on transplant hospitals, although redistribution of organs could affect transplant program volumes. Broader sharing could also affect transplant hospital costs due to higher OPO and travel costs.

Projected Impact on the OPTN

The OPTN supported Committee meetings as well as drafting, review, and revisions of proposed policy changes. This proposal would require implementation of policy changes and communication and education to members.

Post-implementation Monitoring

Member Compliance

The Final Rule requires that allocation policies "include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program."[56] The OPTN will continue to review deceased donor match runs that result in a transplanted organ to ensure that organs have been allocated according to OPTN policy and will continue to investigate potential policy violations.

Policy Evaluation

The Final Rule requires that allocation policies "be reviewed periodically and revised as appropriate."[57] This policy will be formally evaluated at approximately 6 months and 1 year post-implementation. The following metrics, and any metrics subsequently requested by the committee, will be evaluated as data become available (appropriate lags will be applied, per typical OPTN conventions, to account for the time delay in institutions reporting data) and compared to an appropriate pre-policy cohort to assess performance before and after implementation and board approval of this policy, where appropriate. Timeline is subject to change based on the results.

The following metrics will be evaluated overall and across OPTN regions for SLK and kidney-alone registrations and recipients:

- The number of registrations added to the OPTN Waiting List and of those, the proportion who receive a transplant
- The distance between donor and transplant hospital for transplant recipients
- The proportion of registrations removed from the OPTN Waiting List due to death or too sick

[56] 42 CFR §121.8(a)(7).
[57] 42 CFR §121.8(a)(6).

- The distribution of lab MELD or PELD score at transplant for SLK recipients
- The distribution of allocation MELD or PELD score at transplant for SLK recipients
- The distribution of the KDPI of donor kidneys (0-20%, 21-34%, 35-85%, 86-100%)
- The distribution of age (0-2, 3-6, 7-11, 12-17, 18-34, 35-49, 50-64, 65+) at listing and transplant for OPTN Waiting List additions and transplants

Conclusion

The Committee proposes expanding the distance threshold for required simultaneous liver-kidney offers from 250 NM to 500 NM for candidates with MELD of 29 or greater and candidates assigned to liver Status 1A or 1B. The Committee also proposes a number of non-substantive changes to align SLK policy with other OPTN policies and to improve clarity on an OPO's obligation under the policy. Based on current OPO practice, this policy change is not expected to greatly increase liver-kidney transplants, and is not expected to have a large impact on access to kidney-alone or pancreas-kidney transplantation. However, this policy change would make it more likely that candidates requiring a simultaneous liver-kidney transplant are able to receive offers for the organs they need.

Considerations for the Community

The Committee requests feedback on the following questions:

- Do you anticipate any unintended consequences of expanding required SLK shares from 250 NM to 500 NM for certain adult liver-kidney candidates?
- Does the proposed expansion of required SLK shares to 500 NM appropriately balance access to transplant between liver-kidney candidates, other multi-organ candidates who need a kidney, and kidney-alone candidates?
- After the OPO completes required offers to qualifying SLK candidates, should the OPO be required to offer the kidney to kidney-alone candidates, or should the OPO be able to offer the kidney in accordance with any other policy? Similarly, should the OPO be required to offer the liver to liver-alone candidates, or should the OPO be able to offer the liver in accordance with any other policy?
- Do the non-substantive changes to policy provide clear direction to OPOs regarding their obligation under the policy, while also providing OPOs enough flexibility to manage dynamic allocation scenarios?
- Are there other aspects of simultaneous liver-kidney policy that the Committee should clarify further?

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

9.9 Liver-Kidney Allocation

Unless otherwise stated, all mentions of MELD in this section reference a candidate's allocation MELD score.

~~If a host OPO is offering a kidney and a liver from the same deceased donor~~When an OPO is offering a liver, and a kidney is also available from the same deceased donor, then before allocating the kidney to kidney alone candidates, the ~~host~~ OPO must offer the kidney ~~with the liver to candidates~~ to a potential transplant recipient (PTR) who is registered for a liver and a kidney at the same transplant hospital, ~~who meet eligibility criteria according to *Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation*~~ and who meets one of the following criteria:

a. PTR was less than 18 years old when registered on the liver waiting list
b. PTR is registered at a transplant hospital at or w~~W~~ithin 150 nautical miles of the donor hospital and ~~have~~ has a MELD ~~or PELD~~ of 15 or ~~higher~~ greater and meets eligibility criteria according to *Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation*
c. PTR is registered at a transplant hospital at or w~~W~~ithin ~~250~~500 nautical miles of the donor hospital and ~~have~~ has a MELD ~~or PELD~~ of ~~at least~~ 29 or greater and meets eligibility criteria according to *Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation*
d. PTR is registered at a transplant hospital at or w~~W~~ithin ~~250~~500 nautical miles of the donor hospital and is status 1A or 1B and meets eligibility criteria according to *Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation*

The ~~host~~ OPO may then ~~do *either* of the following~~: ~~O~~offer the kidney and liver to any ~~candidates~~PTRs who meet eligibility criteria in *Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation*, or offer the liver and the kidney separately according to policy.

~~a. Offer the liver to liver alone candidates according to *Policy 9: Allocation of Livers and Liver-Intestines*.~~
~~b. Offer the kidney to kidney alone candidates according to *Policy 8: Allocation of Kidneys*.~~

~~*9.9.A Liver-Kidney Candidate Eligibility for Candidates Less than 18 Years Old*~~

~~Candidates who are less than 18 years old when registered on the liver waiting list are eligible to receive a liver and kidney from the same deceased donor when the candidate is registered on the waiting list for both organs. Before allocating the kidney to kidney alone candidates, the host OPO must offer the kidney with the liver to all candidates less than 18 years old at the time of registration.~~

~~*9.9.B Liver-Kidney Candidate Eligibility for Candidates 18 Years or Older*~~

~~Candidates who are 18 years or older when registered on the liver waiting list are eligible to receive both a liver and a kidney from the same deceased donor when the candidate is registered on the waiting list for both organs and meets at least *one* of the criteria according to *Table 9-17* below.~~

Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation

If the candidate's transplant nephrologist confirms a diagnosis of:	Then the transplant program must report to the OPTN and document in the candidate's medical record:
Chronic kidney disease (CKD) with a GFR less than or equal to 60 mL/min for greater than 90 consecutive days	At least *one* of the following: • That the candidate has begun regularly administered dialysis as an end-stage renal disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting. • At the time of registration on the kidney waiting list, that the candidate's most recent GFR or measured or estimated creatinine clearance (CrCl) is less than or equal to 30 mL/min. • On a date after registration on the kidney waiting list, that the candidate's GFR or measured or estimated CrCl is less than or equal to 30 mL/min.
Sustained acute kidney injury	At least *one* of the following, or a combination of *both* of the following, for the last 6 weeks: • That the candidate has been on dialysis at least once every 7 days. • That the candidate has a GFR or measured or estimated CrCl less than or equal to 25 mL/min at least once every 7 days. If the candidate's eligibility is not confirmed at least once every seven days for the last 6 weeks, the candidate is not eligible to receive a liver and a kidney from the same donor.
Metabolic disease	A diagnosis of at least *one* of the following: • Hyperoxaluria • Atypical hemolytic uremic syndrome (HUS) from mutations in factor H or factor I • Familial non-neuropathic systemic amyloidosis • Methylmalonic aciduria

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