OPTN

Briefing to the OPTN Board of Directors on

Expand Required Simultaneous Liver-Kidney Allocation

OPTN Ad Hoc Multi-Organ Transplantation Committee

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Expand Required Simultaneous Liver-Kidney Allocation

Affected Policies: *9.9: Liver-Kidney Allocation*
Sponsoring Committee: *Ad Hoc Multi-Organ Transplantation*
Public Comment Period: *January 19, 2023-March 18, 2023*
Board of Directors Meeting: *June 26, 2023*

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

In an effort to address the unique needs of candidates experiencing multi-organ failure, the OPTN has historically required the allocation of multiple organs from the same donor to multi-organ candidates meeting specific criteria. Receiving organs from the same donor, rather than from multiple donors, may reduce the level of the recipient's immune system response and lower the risk of rejection.[1] 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.

In 2017, the OPTN implemented a SLK policy that based allocation on specific medical criteria and kidney dysfunction rather than liver medical urgency.[2] This policy change was the result of concerns from the community about the increasing volume of SLK transplants.[3] This 2017 policy put in place certain geographic allocation restrictions based on the donor hospital's donation service area (DSA) and OPTN Region. These geographic restrictions changed in 2018 when the OPTN removed the use of DSA and OPTN regions from liver and intestine allocation in favor of Acuity Circles (AC). Accordingly, the OPTN Liver and Intestinal Organ Transplantation Committee, in consultation with the OPTN Kidney Transplantation Committee, updated SLK allocation to reflect these geographic changes. This SLK policy, still in effect, did not change the kidney medical eligibility criteria for candidates but did add three new mandatory sharing categories for OPOS when allocating to candidates seeking a kidney with a liver:

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

The 150 NM and 250 NM circles were selected to maintain similar geographic restrictions that existed in the previous SLK policy.[4]

[1] 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.

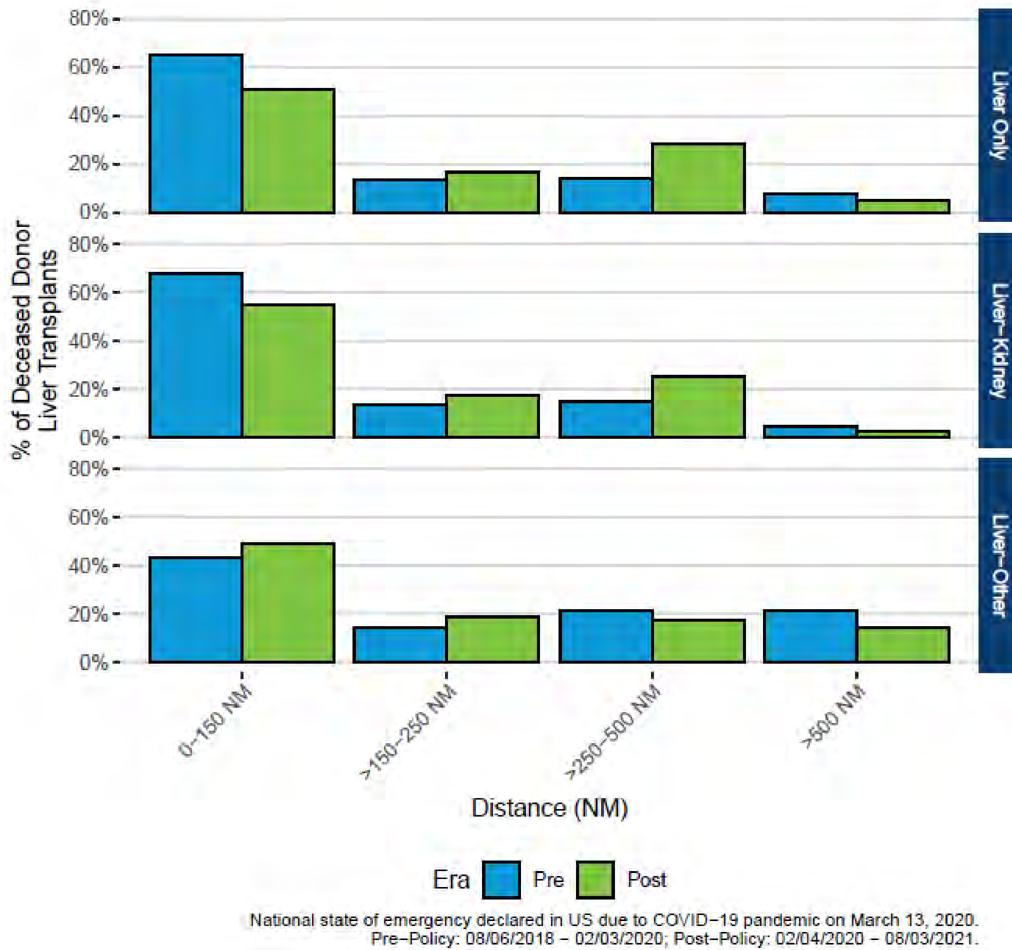
[2] "Simultaneous liver-kidney allocation 2016," OPTN, accessed November 7, 2021, https://optn.transplant.hrsa.gov/governance/public-comment/simultaneous-liver-kidney-allocation-2016/.

[3] 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.

[4] 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

If the SLK offer is not accepted for candidates meeting these criteria, the current policy allows the OPO to continue to offer the kidney along with the liver to candidates who meet the criteria, 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 and the kidney to kidney-alone candidates. As shown in **Figure 1**, OPTN data reflects that OPOs sometimes offer the kidney along with the liver between 250 to 500 NM from the donor hospital as SLK transplants occur within this range. Yet because the decision to allocate at this range is left to the discretion of the individual OPO, an SLK candidate who meets the clinical eligibility criteria could be precluded from accessing the required organs in a timely and equitable fashion.

Figure 1. Deceased Donor Liver Transplants by Multi-Organ Type, Classification Distance, and Era[5]



[5] OPTN data collected prior to 2018 allocation change, and post 2018 allocation change.

In February 2022, to better align with heart allocation policy the OPTN expanded required shares for simultaneous heart-kidney (SHK) and simultaneous lung-kidney (SLuK); both combinations now allocate out to 500 NM for candidates who meet certain medical criteria.[6] That policy was updated in June 2022 adding additional medical eligibility criteria related to kidney dysfunction modeled off current SLK eligibility criteria and these changes will be implemented in 2023.[7] 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 continuous distribution of lungs framework.

Following the approval of SHK and SLuK policies, OPTN members have expressed concern that the distance for SLK required shares only extend out to 250 NM, whereas SHK extend out to 500 NM. While OPOs sometimes offer the kidney with the liver beyond 250 NM, sometimes they do not. Members of the OPTN Liver and Intestinal Organ Transplantation Committee noted instances where OPOs have allocated a liver-alone but not a SLK combination to candidates meeting the MELD threshold and kidney dysfunction criteria in OPTN policy, but who are registered at a transplant hospital beyond 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.[8] 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.

Proposal for Board Consideration

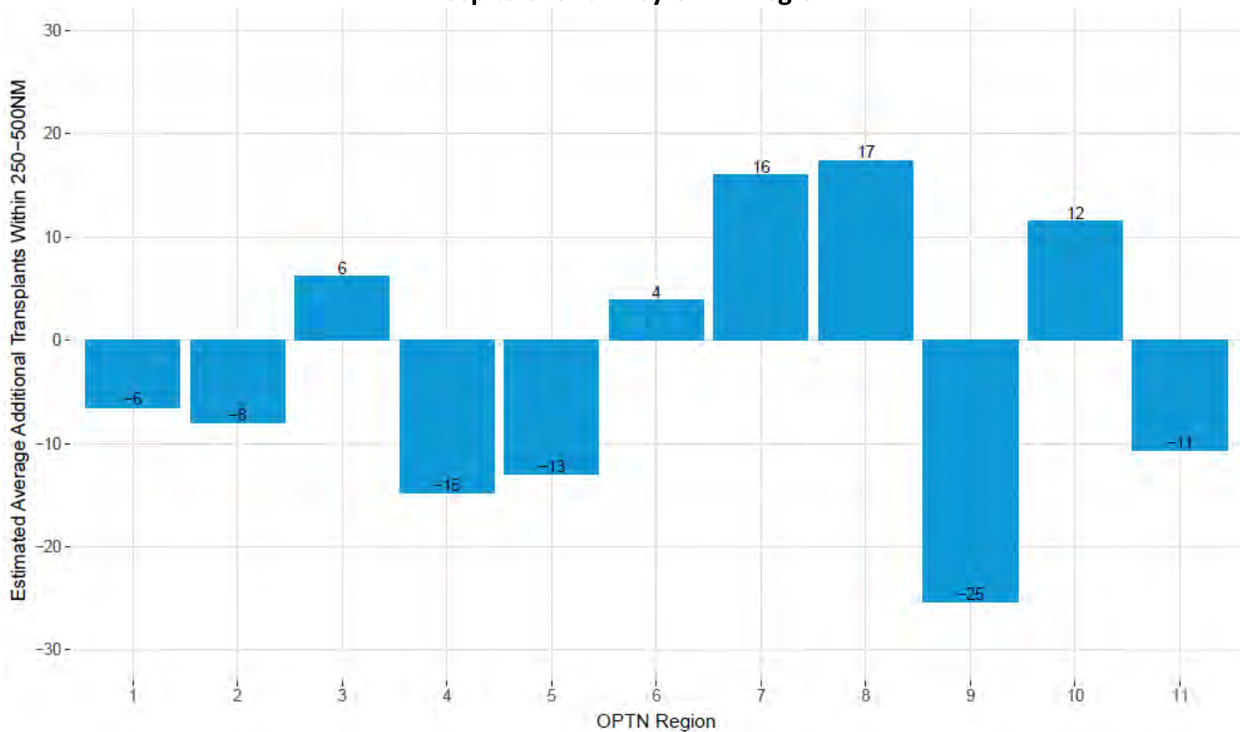
Required SLK Expansion

The Ad Hoc Multi-Organ Transplantation Committee, the Committee, is proposing expanding the geographic threshold for required simultaneous liver-kidney offers from 250 NM to 500 NM from the donor hospital. This would be for pediatric candidates and adult candidates with MELD of 29 or greater, and for candidates assigned to liver Status 1A. The Committee also proposes updating the policy so that the OPO may offer the 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.

[6] "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.
[7] "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.
[8] 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.

Concerns raised during public comment focused on three key areas of impact: kidney-alone candidates, pediatric candidates, and geographic logistic concerns. Data obtained by the Committee during its drafting of the proposal suggests increasing the geographic threshold to 500 NM will have minimal impact on kidney-alone candidates gaining access to organs. This is largely due to the fact that OPOs are currently allowed to allocate the liver with the kidney beyond 250 NM, and many OPOs choose to do so. **Figure 2** shows the anticipated difference in SLK transplant with a hypothetical geographic minimum of 500 NM. The regions in the figure shown with a negative estimate are already allocating the liver with the kidney beyond 250 NM.[9] The data also suggests that SLK allocation would remain relatively unchanged across all combined regions upon implementation of this policy.[10]

Figure 2. The Estimated Number of Additional Transplants between 250 and 500 NM of Donor Hospitals for SLK by OPTN Region



The same is true for pediatric candidates. The geographic concerns centered largely on the increased cost for transporting organs an additional distance and the cold ischemic time (CIT) placed on the organs during travel and allocation. Again, many OPOs are already allocating the kidney with the liver, as well as other organs at the proposed 500 NM distance, so the increased cost for transport or CIT is not anticipated to be substantial.

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[9] Counterfactual estimated average number of SLK transplants that could occur between 250-500 NM if the required share circle size had been 500 NM instead of 250 NM, 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. This table also shows the difference between the ~~the~~ estimated counterfactual average and the observed average number of transplants that occurred between 250-500 NM to approximate the average number of additional transplants that could occur between 250-500 NM if the required share circle size had been 500 NM instead of 250 NM. Because organ procurement organizations (OPOs) are currently permitted to share between 250-500 NM, the difference between the counterfactual estimated average number of transplants and the observed average number of transplants that occurred between 250-500 NM can be less than, greater than, or equal to zero. Values less than zero suggest that the observed number of transplants seen between 250-500 NM exceeds what would be expected based on the transplant-to-waiting ratio seen within 250 NM; conversely, values greater than zero suggest that the observed number of transplants seen between 250-500 NM is less than what would be expected based on the transplant-to-waiting ratio seen within 250 NM.

[10] OPTN Data Request Analysis-SLK Transplants, Presented to the OPTN Ad-Hoc Multi-Organ Transplantation Committee, November 7, 2022.

The Committee determined that the need to align allocation practices and better serve candidates outweighed those specific concerns. Additionally, the concerns are already being addressed by many OPOs who currently allocate the kidney with the liver out to 500 NM. No substantive policy changes are proposed following public comment.

Non-substantive Policy Changes

This proposal also includes non-substantive changes made to policy language. None of the non-substantive changes proposed by the Committee modify the OPO's obligation under the policy. These non-substantive changes were not addressed by any participant during public comment. The Committee itself did find one redundant qualifier within the policy language during the public comment period. Liver status 1B is reserved for pediatric patients, being a pediatric patient at the time of registration is already listed as a criterion within the policy. This makes the use of the term "status 1B" within another criterion redundant and unnecessary. The Committee has chosen to remove this specific reference to status 1B. No other changes have been made to the non-substantive portion of the proposal.

Overall Sentiment from Public Comment

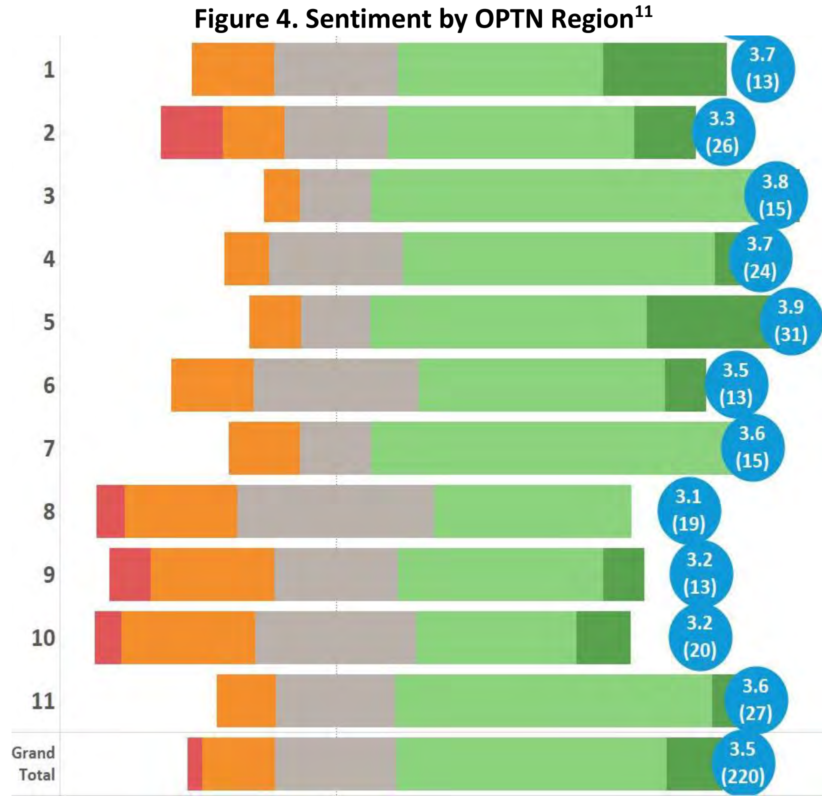
This proposal was open for public comment from January 19, 2023, to March 18, 2023. It was a discussion agenda item at all OPTN Regional Meetings. It was also reviewed by the OPTN Kidney Transplantation Committee, Pediatric Committee, Transplant Coordinators Committee, Liver and Intestines Committee, Transplant Administrators Committee, and Organ Procurement Organization Committee. Overall, this proposal was reviewed by 232 participants during public comment. As **Figure 3** illustrates, comments were received from all member types, with the greatest participation coming from transplant hospitals.

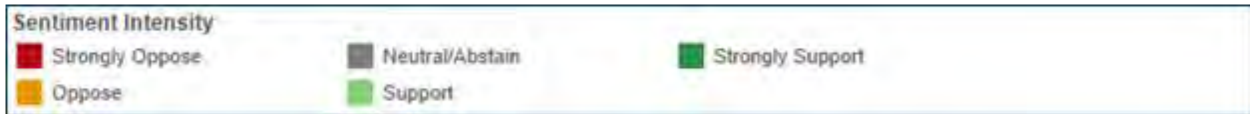
Figure 3. Number of Comments Received by OPTN Member Type

OPTN Member Type	Number of Comments Received
Transplant hospital	120
Organ procurement organization	46
Histocompatibility lab	25
Member type not provided	18
Candidate, recipient, living donor, candidate family, recipient family, donor family	14
Stakeholder organization	9
Non-OPTN member	1
Total	**232**

The proposal scored 3.5 out of 5 in overall sentiment, which means the community is generally supportive of this proposal. **Figure 4** shows the sentiment score by OPTN region. The lowest sentiment score of any OPTN region was region 8 with a score of 3.1. Region 8 is projected to see an increase in SLK allocation upon implementation of this policy.

Figure 4. Sentiment by OPTN Region[11]

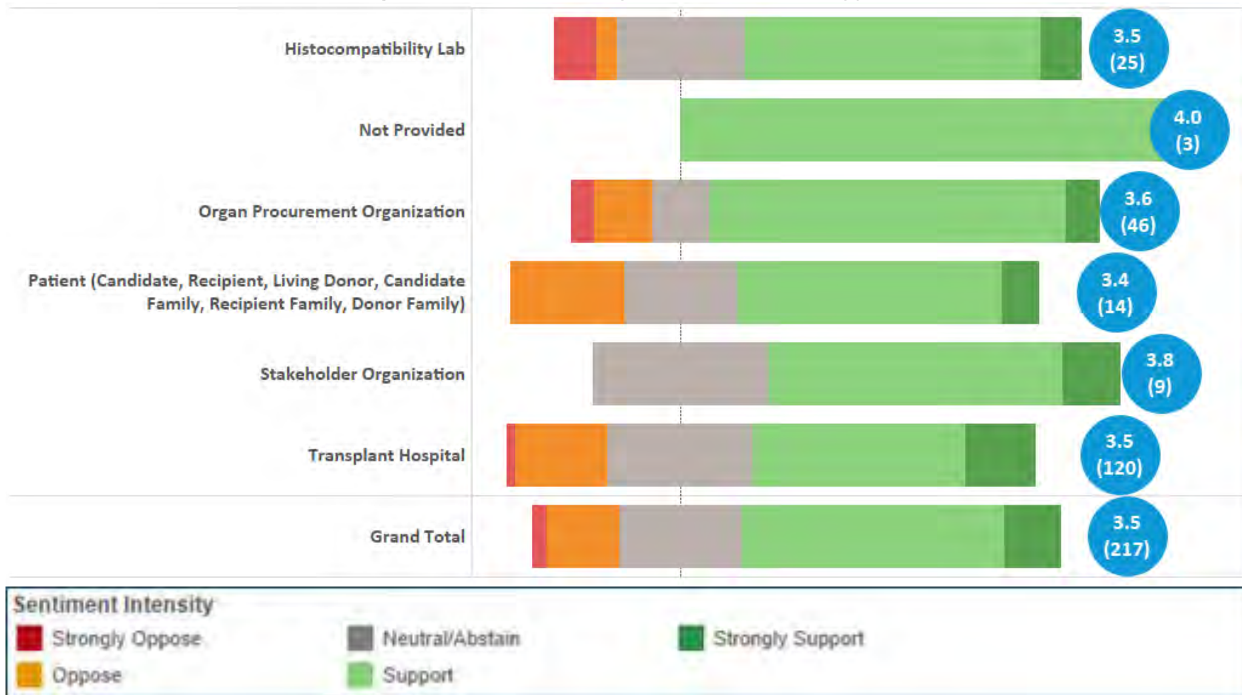




The sentiment by member type is shown in **Figure 5.** Of those who provided the information was the highest among stakeholder organizations and OPOs. OPOs appreciate the alignment of multi-organ allocation this policy will provide. The lowest sentiment scores were provided by those identifying themselves within the patient category, 3.4, who voiced concerns on the impact this policy could have on single organ candidates and prior living donors.

[11] OPTN Public Comment data January 19, 2023 -March 18, 2023.

Figure 5. Sentiment by OPTN Member Type[12]



The sentiment by member type of those who provided the information was the highest among stakeholder organizations and OPOs. OPOs appreciate the alignment of multi-organ allocation this policy will provide. The lowest sentiment scores were provided by those identifying themselves within the patient category, 3.4, who voiced concerns on the impact this policy could have on single organ candidates and prior living donors.

The comments focused on concern for kidney-alone and pediatric candidates within 250 NM from the donor hospital being bypassed in favor of multi-organ candidates further away. There was also concern expressed by regional and OPTN committee members regarding logistical issues with the increased geographic distance, but there was also an understanding by regional meeting participants this change is necessary for equity purposes.[13] There were multiple comments from members and partner organizations in favor of this proposal because of the consistency in allocation it provides for OPOs.

Compliance Analysis

NOTA and OPTN Final Rule

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."[14] The OPTN Final Rule states the OPTN "shall be responsible for

[12] OPTN Public Comment data January 19, 2023 -March 18, 2023.
[13] OPTN Public Comment "Expand Required Simultaneous Liver-Kidney Allocation." OPTN Region 11 Meeting, March 1, 2023. https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/expand-required-simultaneous-liver-kidney-allocation/

[14] 42 USC §274(b)(2)(B).

developing…policies for the equitable allocation for cadaveric organs."[15] 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."[16] This proposal:

- **Is based on sound medical judgment:[17]** 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.[18] Current policy allows for SLK allocation beyond 250 NM, but it is not required. This policy change would allow for greater utilization of organs by expanding the minimum geographic distance of allocation.
- **Seeks to achieve the best use of donated organs:[19]** 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.[20] 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.[21,22] 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.

[15] 42 CFR §121.4(a)(1).
[16] 42 CFR §121.8(a).
[17] 42 CFR §121.8(a)(1).
[18] 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.
[19] 42 CFR §121.8(a)(2).
[20] "Simultaneous Liver Kidney (SLK) Allocation," OPTN, Briefing Paper, accessed November 20, 2022, https://optn.transplant.hrsa.gov/media/1871/kidney_briefingpaper_slk_201606.pdf.
[21] Ibid.
[22] Sharma et al., "Propensity Score-Based Survival Benefit," 77.

- **Is designed to…promote patient access to transplantation[23] 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 eligibility criteria for SLK offers but are located beyond 250 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.[24]
- **Promotes the efficient management of organ placement[25] 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.[26] 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,[27] and it is specific to a combination of organ types, in this case liver-kidney.[28]

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[29]
- Is designed to avoid futile transplants[30]

[23] Id.
[24] "Ethical Implications of Multi-Organ Transplants," OPTN, White Paper, accessed November 20, 2022, https://optn.transplant.hrsa.gov/media/2989/ethics_boardreport_201906.pdf.
[25] Id.
[26] 42 CFR §121.8(a)(8)
[27] 42 CFR §121.8(a)(3).
[28] 42 CFR §121.8(a)(4).
[29] 42 CFR §121.8(a)(5).
[30] Id.

OPTN Strategic Plan

The OPTN Strategic Plan seeks to improve equity in access, particularly for multi-organ candidates.[31] This proposal addresses this component of the strategic plan by allowing for greater access to organs for multi-organ candidates who are located beyond 250 NM from the donor hospital. This also addresses the OPTN Strategic plan by addressing a disparity in multi-organ allocation based on geography. [32]Currently, some multi-organ candidates are receiving offers from beyond 250 NM, while other candidates are not. The proposal seeks to eliminate this disparity by requiring allocation of kidney with liver beyond 250 NM, aligning it with other multi-organ combinations.

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.

Organ Procurement Organizations

Operational Considerations

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

Fiscal Impact

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

Transplant Programs

Operational Considerations

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.

Fiscal Impact

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.

[31] "OPTN Strategic Plan 2021-2024," OPTN Executive Committee. Pg. 6. https://optn.transplant.hrsa.gov/media/4355/2021_2024_optn_strategic_plan_proposal.pdf

[32] OPTN Tab.

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.

OPTN

Operational Considerations

The OPTN is working sequentially to consider continuous distribution allocation systems for deceased donor organs.[33] 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.[34] 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.

Resource Estimates

The OPTN Contractor estimates 575 hours for implementation. Implementation will involve updates to OPTN computer system to incorporate new data fields and match run practices. The OPTN contractor estimates 170 hours for ongoing support. Ongoing support includes the creation of new educational resources for OPOs and transplant centers regarding the new allocation practices.

[33] "Continuous Distribution," OPTN, accessed January 24, 2022, https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/.
[34] "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/.

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."[35] 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."[36] 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
- 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 pediatric candidates. 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. Following public comment, no substantive changes were necessary. A small substantive change which removed an unnecessary redundancy for status 1B was made. 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

[35] 42 CFR §121.8(a)(7).
[36] 42 CFR §121.8(a)(6).

change would make it more likely that candidates requiring a simultaneous liver-kidney transplant are able to receive offers for the organs they need.

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.

1 **9.9 Liver-Kidney Allocation**

2 Unless otherwise stated, all mentions of MELD in this section reference a candidate's allocation MELD
3 score.
4
5 ~~If a host OPO is offering a kidney and a liver from the same deceased donor~~. When an OPO is offering a
6 liver, and a kidney is also available from the same deceased donor, then before allocating the kidney to
7 kidney alone candidates, the ~~host~~ OPO must offer the kidney ~~with the liver to candidates~~ to a potential
8 transplant recipient (PTR) who is registered for a liver and a kidney at the same transplant hospital, ~~who~~
9 ~~meet eligibility criteria according to *Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation*~~ and
10 who meets one of the following criteria:

11 a. PTR was less than 18 years old when registered on the liver waiting list
12 b. PTR is registered at a transplant hospital at or w~~W~~ithin 150 nautical miles of the donor
13 hospital and ~~have~~ has a MELD ~~or PELD~~ of 15 or ~~higher~~ greater and meets eligibility criteria
14 according to *Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation*
15 c. PTR is registered at a transplant hospital at or w~~W~~ithin ~~250~~500 nautical miles of the donor
16 hospital and ~~have~~ has a MELD ~~or PELD~~ of ~~at least~~ 29 or greater and meets eligibility criteria
17 according to *Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation*
18 d. PTR is registered at a transplant hospital at or w~~W~~ithin ~~250~~500 nautical miles of the donor
19 hospital and is adult status 1A and meets eligibility criteria according to *Table 9-17: Medical*
20 *Eligibility Criteria for Liver-Kidney Allocation*
21
22 The ~~host~~ OPO may then ~~do *either* of the following~~: ~~O~~offer the kidney and liver to any ~~candidates~~PTRs
23 who meet eligibility criteria in *Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation*, or offer
24 the liver and the kidney separately according to policy.
25 ~~a. Offer the liver to liver alone candidates according to *Policy 9: Allocation of Livers and Liver-*~~
26 ~~*Intestines*.~~
27 ~~b. Offer the kidney to kidney alone candidates according to *Policy 8: Allocation of Kidneys*.~~
28
29 ~~*9.9.A Liver-Kidney Candidate Eligibility for Candidates Less than 18 Years Old*~~

30 ~~Candidates who are less than 18 years old when registered on the liver waiting list are eligible to~~
31 ~~receive a liver and kidney from the same deceased donor when the candidate is registered on~~
32 ~~the waiting list for both organs. Before allocating the kidney to kidney alone candidates, the~~
33 ~~host OPO must offer the kidney with the liver to all candidates less than 18 years old at the time~~
34 ~~of registration.~~
35
36 ~~*9.9.B Liver-Kidney Candidate Eligibility for Candidates 18 Years or Older*~~

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

41

42 **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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