OPTN

Briefing to the OPTN Board of Directors on

Clarify Multi-Organ Allocation Policy

OPTN Organ Procurement Organization Committee

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Clarify Multi-Organ Allocation Policy

Affected Policies:	*5.10.C: Other Multi-Organ Combinations*
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Sponsoring Committee:	*Organ Procurement Organization*
Public Comment Period:	*January 21, 2021 – March 23, 2021*
Board of Directors Date:	*June 14, 2021*

Executive Summary

Multi-organ allocation policies have been an area of concern for many years. The OPTN Ethics Committee developed a white paper to provide guidance on multi-organ transplant policy and practice.[1] The Board of Directors approved this white paper in June 2019. In 2019, the OPTN Policy Oversight Committee (POC) began developing strategic policy priorities. One of the priorities identified and approved by the OPTN Executive Committee was to improve equity for multi-organ and single organ candidates.[2] A multi-disciplinary workgroup was formed to begin addressing multi-organ allocation policies to improve consistency and transparency in current general multi-organ policy.[3]

This proposal addresses the first step of this strategic policy priority by clarifying *OPTN Policy 5.10.C: Other Multi-Organ Combinations*. The current policy addresses multi-organ combinations for candidates on the heart, lung, or liver waiting list that require a second organ. Current policy does not address which match run is used or provide specifics about the "second required organ." This leads to inconsistent application of the requirements outlined in this policy.

The OPO Committee submits this proposal under the authority of the OPTN Final Rule, as part of development of "policies for the equitable allocation of cadaveric organs."[4]

The OPO Committee proposes the following criteria for when OPOs are required to offer the liver or kidney, if available, from the same donor to a potential transplant recipient registered at a transplant hospital within 500 nautical miles (NM) of the donor hospital:

- Heart adult status 1, 2, 3, or any active pediatric heart candidates
- Lung candidates with a lung allocation score (LAS) greater than or equal 35 or active candidates less than 12 years old

Of note, the proposed distance for this mandatory offer will be increased from the current 250 NM for heart and lung to a 500 nautical mile circle for heart and lung multi-organ candidates to better align with thoracic allocation policies. After considerable feedback collected in the public comment period, the OPO Committee expanded the originally proposed criteria to include all active pediatric heart candidates and all lung candidates under 12 years of age.

[1] https://optn.transplant.hrsa.gov/media/2801/ethics_publiccomment_20190122.pdf
[2] https://optn.transplant.hrsa.gov/media/3615/20191008_exec_comm_summary.pdf
[3] https://optn.transplant.hrsa.gov/media/3005/201906_board_executivesummary.pdf
[4] 42 CFR §121.4(a)(1)

Background

In 2019, the OPTN Policy Oversight Committee (POC) began developing strategic policy priorities. The criteria for strategic policy priorities included the following:

- Impact to multiple organ systems
- Impact to multiple member types
- Require expertise from multiple committees and stakeholder organizations
- Require changes to multiple policies to provide consistent approach
- Results in large-scale improvement to deliver the greatest benefit to the community.

One of the priorities identified and approved by the OPTN Executive Committee was to improve equity for multi-organ and single organ candidates. The initial step in a phased approach to address multi-organ policies is to revise the general multi-organ policy prior to beginning work on any specific multi-organ policies. This will ensure that the specific multi-organ policies are consistent with the general multi-organ policy. The next phase of this effort will be to address other multi-organ combinations, with eligibility criteria for heart-kidney identified as the next step.

OPTN Policy 5.10.C: Other Multi-Organ Combinations was modified as part of several recent proposals that removed donation service area (DSA) from heart, lung, and liver allocation policies.[5][6] These changes replaced DSA with 150 nautical miles (NM) for liver and 250NM for lung and heart as the distances for when the OPO is required to offer the second required organ. The intent of these changes was to remove DSA from allocation policy, not to provide new requirements for OPOs when allocating multi-organ combinations. Current policy requires a certain level of interpretation by OPOs, which can lead to inconsistent practice across the country.

While the number of multi-organ combinations not currently addressed in policy are relatively small as illustrated in **Figure 1**, it is important for the Committee to address the combinations in this proposal as part of the phased approach to addressing multi-organ policies. Addressing heart-liver, lung-liver, heart-kidney, and lung-kidney combinations will address 84% of the combinations not currently addressed in other policies.

[5] https://optn.transplant.hrsa.gov/media/2994/thoracic_boardreport_201906.pdf - or *OPTN Thoracic Organ Transplantation Committee Report to the Board of Directors*, OPTN Thoracic Organ Transplantation Committee, June 2019.
[6] https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf or *OPTN Liver and Intestinal Organ Transplantation Committee Report to the Board of Directors*, OPTN Liver and Intestinal Organ Transplantation Committee, December 2018.

Figure 1: Number of Multi-Organ Transplants (2016-2019)

Multi-Organ Transplants					
	2016	2017	2018	2019	Policy?
All deceased donor transplants	27,630	28,588	29,680	32,322	
All Multi-Organ Transplants	1801	1853	1882	1989	
Liver-Kidney	730	739	677	727	Yes
Kidney-Pancreas	798	789	835	872	Yes
Heart-Kidney	140	187	203	219	No
Liver-Intestine-Pancreas	58	55	51	35	No
Liver-Heart	18	29	39	45	No
Heart-Lung	18	29	32	45	Yes
Liver-Lung	9	8	14	12	No
Intestine-Pancreas	8	3	4	5	No
Kidney-Intestine	5	1	2	3	No
Kidney-Lung	4	7	9	13	No
Liver-Pancreas	3	1	2	1	No
Liver-Intestine	2	0	3	1	Yes
Liver-Kidney-Heart	1	0	3	6	No
Liver-Kidney-Intestine-Pancreas	7	2	7	4	No
Kidney-Heart-Lung	0	2	2	1	No
Liver-Pancreas-Lung	0	0	0	0	No
Liver-Kidney-Pancreas	0	0	0	0	No
Kidney-Intestine-Pancreas	0	0	0	0	No
Liver-Kidney-Intestine	0	0	0	0	No
Heart-Pancreas	0	0	0	0	No
Liver-Heart-Lung	0	1	0	0	No
https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/					

A multi-disciplinary workgroup (Workgroup) was formed with representation from the following OPTN committees:

- Organ Procurement Organization
- Liver and Intestinal Organ Transplantation
- Heart Transplantation
- Lung Transplantation
- Kidney Transplantation
- Pancreas Transplantation
- Pediatric Transplantation
- Transplant Coordinators
- Vascular Composite Allograft
- Ethics
- Patient Affairs

Purpose

The purpose of this proposal is to provide OPOs with clearer direction when offering multi-organ combinations by establishing criteria for when OPOs must offer the liver or kidney to heart or lung candidates listed for these organs.

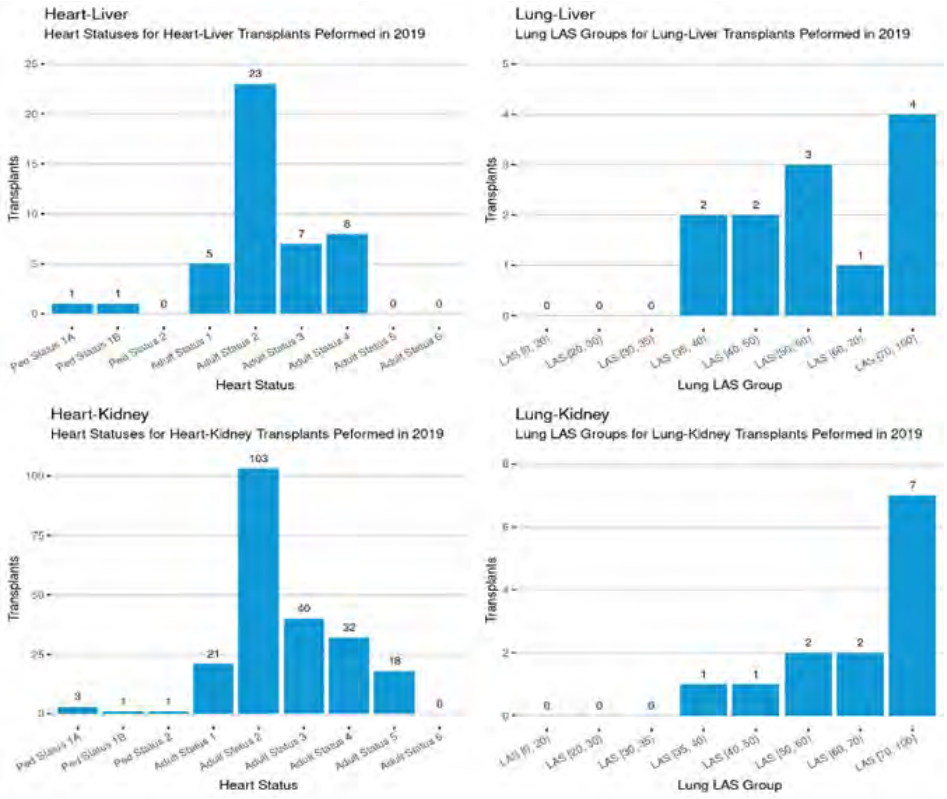
Proposal for Board Consideration

The OPO Committee proposes adding medical criteria and increasing the distance for heart and lung candidates that require a second organ, which is identified as a kidney or a liver. The criteria will establish requirements for when OPOs must offer the second organ to the same candidate when allocating the heart or the lung. The Committee is also proposing clarity that the heart, heart-lung, and lung match runs will drive the allocation of these combinations.

Heart and Lung Multi-Organ Criteria

The workgroup reviewed data on the statuses of multi-organ candidates who received heart-liver, lung-liver, heart-kidney, or lung-kidney transplants in 2019.[7] **Figure 5** shows the recipient statuses for these combinations of multi-organ transplants.

Figure 5: Recipient Statuses at Transplant (2019)



The Committee proposes the following criteria for heart and lung candidates to receive offers for either a kidney or liver, if listed for a second organ:

- Heart Adult Status 1, 2, and 3, Pediatric Status 1A, 1B, and 2
- Lung Candidates with a lung allocation score of greater than 35 or candidates less than 12 years old

[7] See Multi-Organ Policy Workgroup Meeting Summary, May 29, 2020. Available at https://optn.transplant.hrsa.gov/

The statuses were determined based on the data shown in **Figure 5.** The higher status heart and lung candidates are admitted to the hospital, as required in *Policy 6: Allocation of Hearts and Heart-Lungs* and *Policy 10: Allocation of Lungs*. These criteria were expanded to include heart pediatric status 2 and all lung candidates less than 12 years old after significant support for inclusion of pediatric heart candidates and lung multi-organ candidates under 12 years old was gathered during the public comment period.[8] The overall numbers for pediatric heart-liver and heart-kidney transplants, as well as lung-liver and lung-kidney transplants under 12 years old, are very small, but very critical to the individual recipient. The Ethical principles of pediatric organ allocation white paper describes pediatric candidates as "particularly vulnerable and in need of expeditious transplant" due to "diminished quality of life during development, age and size-specific barriers to transplant, unique challenges in providing life sustaining therapy for pediatric patients awaiting transplant, and the risk of premature death."[9] Across unique utility benefits and ethical implications, the OPTN Ethics Committee found "reasonable basis for pediatric preference in allocation."[10] Similarly, the National Organ Transplant Act (NOTA) mandates the OPTN to "adopt criteria, policies and procedures that address the unique healthcare needs of children."[11] The inclusion of all heart pediatric candidates and lung candidates under 12 aligns with both the principles presented in the Ethical principles of pediatric organ allocation white paper and the requirements and obligations of the OPTN under NOTA.

For multi-organ transplants performed in 2019, the following multi-organ transplants would meet the proposed criteria:

- Heart-liver transplants - 37 of 45
- Heart-kidney – 169 of 219
- Lung-liver – 12 of 12
- Lung-kidney – 13 of 13

Feedback gathered in the public comment period reflected some concern for heart status 4 candidates, particularly those with Fontan physiology who may not particularly benefit from inotropic support but still may need a liver or kidney. McCormick and Schumacher[12] note that patients living with Fontan physiology, a palliative procedure for congenital heart disease patients, have high rates of liver and kidney disease. Some members also cited Kobashigawa et al.[13] who recommended that a kidney be offered to any heart-kidney candidate with a glomerular filtration rate (GFR) less than 30 mL/min. The

[8] The Committee sought feedback during the public comment period on specific questions, including "Is Heart Adult Status 1, 2, 3 and Pediatric Status 1A and 1B appropriate thresholds for when OPOs must offer a liver or kidney to a multi-organ candidate listed for those organs?" and "Is a lung allocation score of greater than 35 an appropriate threshold for when OPOs must offer a liver or kidney to a multi-organ candidate listed for those organs?"
Clarify Multi-Organ Allocation Policy, OPTN Organ Procurement Organization Committee, January 2021, https://optn.transplant.hrsa.gov/media/4354/2021_pc_opo_clarify_multi_organ_allocation_policy.pdf

[9] *Ethical principles of pediatric organ allocation*, OPTN Ethics Committee, November 2014, https://optn.transplant.hrsa.gov/media/2989/ethics_boardreport_201906.pdf

[10] *Ethical principles of pediatric organ allocation*, OPTN Ethics Committee, November 2014, https://optn.transplant.hrsa.gov/media/2989/ethics_boardreport_201906.pdf

[11] National Organ Transplantation Act of 1984, 42 USC §274(b)(2)(m)

[12] McCormick, A. D., & Schumacher, K. R. (2019). Transplantation of the failing Fontan. Translational pediatrics, 8(4), 290–301. https://doi.org/10.21037/tp.2019.06.03

[13] Kobashigawa J, Dadhania DM, Farr M, Tang WHW, Bhimaraj A, Czer L, Hall S, Haririan A, Formica RN, Patel J, Skorka R, Fedson S, Srinivas T, Testani J, Yabu JM, Cheng XS; Consensus Conference Participants. Consensus conference on heart-kidney transplantation. *American Journal of Transplantation.* 2021 Feb 2. doi: 10.1111/ajt.16512. Epub ahead of print. PMID: 33527725

Committee did not include criteria for the second required organ because this issue will be addressed during the next phase of multi-organ allocation policy discussions.

Community feedback was relatively supportive of the LAS threshold of 35. Some stakeholder members recommended increasing the LAS threshold to 40 or 45, to better match the urgency of heart status 2 and 3 candidates. The Committee originally considered an LAS threshold of 40 but lowered it following feedback from the Lung Committee.

The OPO Committee reviewed and discussed all public comment feedback, and acknowledges that this proposal clarifies current policy but does not address medical eligibility criteria for the liver and kidney. The Committee is committed to both clarifying current policy and working with community stakeholders in the coming effort to pursue eligibility criteria in multi-organ allocation policy.

Several workgroup members were concerned about disadvantaging liver and kidney alone candidates if livers or kidneys are placed with heart or lung candidates listed for a second organ. This concern was echoed considerably during the public comment period. It is important to note that the current policy does not prioritize multi-organ candidates over single organ candidates. Even with the proposed changes, OPOs will still be required to allocate organs according to current *Policy 2.2: OPO Responsibilities*, which states that OPOs execute the match run and use "the resulting match for each deceased donor allocation."

Reese et al. outlined the challenges of appropriately balancing priority between single and multi-organ candidates, specifically maximizing organ utility (defined as optimal patient and graft survival) for single and multi-organ recipients, while also identifying candidates who would benefit most from a multi-organ transplant.[14] For example, a heart status 1 candidate might receive the liver from the same donor regardless of model for end-stage liver disease (MELD) score when there is a higher status liver alone candidate in need of a liver transplant. Though the small population size of multi-organ candidates complicates statistical evaluation, it dampens the effects of multi-organ sharing on single-organ candidate access. Goldberg et al. found that "although transplant is delayed, liver transplant waitlist candidates bypassed by heart-liver recipients do not have excess mortality compared to three sets of matched controls."[15]

Heart and lung candidates also face organ-specific biological disadvantages compared to candidates waiting for other organs. Donor-recipient height, weight, and gender matching are important factors in post-transplant outcomes. While recent publications, such as Eberlein et al., recommend changes to how thoracic organ sizes are measured, "donor-to-recipient organ size matching is a critical aspect of thoracic transplantation."[16] This can limit the number of offers that heart and lung candidates can accept and further impact those candidates needing a liver or kidney. Considerations of these biological disadvantages contributed to the Committee's decision to focus medical criteria for heart and lung candidates.

[14] Reese P, Veatch RM, Abt PL, and Amaral S. Revisiting Multi-Organ Transplantation in the Setting of Scarcity. *American Journal of Transplantation* 14, no. 1 (2013): 21-26. doi:10.1111/ajt.12557

[15] Goldberg DS, Reese PP, Amaral S, Abt PL. Reframing the Impact of Combined Heart-Liver Allocation on Liver Transplant Waitlist Candidates. *Liver Transplantation*. 2014 November; 20(11): 1356–1364. doi:10.1002/lt.23957

[16] Eberlein M, Reed RM. Donor to recipient sizing in thoracic organ transplantation. World Journal of Transplantation, 2016 March 24; 6(1): 155-164

The Committee believes that establishing criteria that provides access to the second organ for sicker heart and lung candidates and priority for pediatric patients aligns with current practice as the community awaits further work on eligibility criteria and safety nets for multi-organ allocation. The intent of this proposal is to provide clearer rules for OPOs when allocating a heart or lung according to the appropriate match run and a heart or lung candidate is listed for a liver or kidney. This proposal also allows OPOs the discretion to determine the best approach to placing organs according to OPTN policy, even if multi-organ candidates do not meet the criteria in this proposal.

Reference to Kidneys

Currently, *Policy 5.10.C: Other Multi-Organ Combinations* does not reference kidneys as the second required organ that must "be allocated to the multi-organ candidate from the same donor" within the geographic areas outlined in the policy. However, *Policy 9.9: Liver-Kidney Allocation* addresses the requirements for OPOs when a kidney is procured along with other organs. The OPO must first offer the kidney according to *Policies 5.10.C*, *9.9*, or *11.4.A: Kidney-Pancreas Allocation* before allocating to kidney alone candidates. This proposal does not affect an OPO's ability to decide which multi-organ policy to utilize when a kidney is procured with other organs.

The Committee agreed that it is common practice for OPOs to allocate the kidney from the same donor if a heart or lung candidate on the match run is also registered for a kidney. The absence of clear requirements in the current policy leads to inconsistent application of the rules. Therefore, the Committee proposes adding specific language addressing kidneys as part of heart-kidney and lung-kidney combinations. The Committee recognizes the impact that allocating kidneys to multi-organ candidates have on kidney alone candidates. A recent publication by Westphal et al. highlighted "the potential for multi-organ transplant prioritization to unintentionally introduce disparities in transplant access for kidney alone candidates."[17] For the Committee, this underscores the importance of addressing equitable multi-organ allocation policies in an era where the need outnumbers the supply to ensure the best use of donated organs.

Community feedback gathered in public comment revealed concern that pediatric, highly sensitized, and low estimated post-transplant survival score candidates will be inappropriately disadvantaged by the proposed policy. Members of the community expressed concern that the average quality of kidneys allocated to multi-organ candidates was relatively higher than those allocated to single-organ kidney recipients.

The Committee acknowledges that this effort clarifies current policy but does not address medical eligibility criteria or a "safety net" as used in current simultaneous liver kidney (SLK) policy. The Committee is committed to clarifying current policy while working with stakeholders across the community during the impending effort to pursue these additional policies. Feedback from the community collected during public comment demonstrated significant support for eligibility criteria and "safety nets" in future stages of multi-organ allocation policy.

[17] Westphal, S. G., Langewisch, E. D., Robinson, A. M., Wilk, A. R., Dong, J. J., Plumb, T. J., Mullane, R., Merani, S., Hoffman, A. L., Maskin, A., & Miles, C. D. (2020). The impact of multi-organ transplant allocation priority on waitlisted kidney transplant candidates. American journal of transplantation : official journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 10.1111/ajt.16390. Advance online publication. https://doi.org/10.1111/ajt.16390

Change to Geographic Unit

The Committee is proposing changes to the distances outlined in current policy. The current distance is 250 nautical miles (NM) for heart and lung and 150 NM for liver, which are the smallest units of allocation for heart, lung, and liver. These distances were established when liver and thoracic policies changed from donation service area (DSA) to distance-based distribution.[18,19,20]

The Committee proposes increasing the distance to 500 NM to better align with current heart allocation. This will allow the candidates with the proposed statuses to access a liver or kidney if needed. For example, the classifications for Status 1 and 1A heart candidates start at 500NM according to *Policy 6.6.D: Allocation of Hearts from Donors at Least 18 Years Old* and *Policy 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old*.

The Committee also proposes 500 NM for lung candidates in order to be consistent within the proposed policy. The allocation of lungs from donors at least 18 years old begins with 250 NM for classifications 1-6 followed by 500 NM for classifications 7-12.[21] The allocation of lungs from donors less than 18 years of age begins with 1000 NM, which presents more logistical challenges when allocating multi-organ combinations. However, the proposed distance of 500 NM does not prevent OPOs from having the discretion to place a kidney or liver with a candidate outside the 500 NM circle.

Community feedback collected through the public comment period was generally supportive of the 500 NM circle expansion.

Clarity on Match Runs

The current policy provides little direction for OPOs regarding which match run to use when allocating multi-organ combinations. While this proposal does not establish OPO requirements for which organs must be allocated first, it does provide clarity that OPOs allocating according to the heart, heart-lung or lung match run must offer the liver or kidney to a candidate listed for the second organ if they meet the proposed criteria. The criteria based on proposed heart statuses, LAS, and 500NM distribution circle will determine when the OPO must offer the second organ. This proposal does not mandate which match run to start with – therefore allowing for OPO discretion.

Feedback collected through public comment encouraged increased efforts to establish priority between multi-organ combinations. The OPO Committee acknowledges that further clarification for multi-organ combination priority will be critical to the coming efforts to improve multi-organ allocation policy and equity for multi-organ candidates.

Other Considerations

The multi-disciplinary workgroup discussed creating policies to require OPOs to allocate organs to higher status kidney or liver alone candidates if no higher status heart or lung candidates required a second

[18] https://optn.transplant.hrsa.gov/media/2788/liver_policynotice_201901.pdf
[19] https://optn.transplant.hrsa.gov/media/3003/thoracic_policynotice_201906.pdf
[20] https://optn.transplant.hrsa.gov/media/2539/thoracic_policynotice_201807_lung.pdf
[21] OPTN Policy 10, Allocation of Lungs (April 15, 2020)

organ. This would be required before allocating the second organ to other multi-organ candidates that do not meet the proposed criteria.

There are several challenges to creating such policy requirements. There is a lack of consistency in organs available per donor as well as the quality of organs. Additionally, there are multiple considerations for how proposed changes may affect other OPTN policies. For example, establishing a mandate that OPOs allocate to kidney alone candidates prior to other multi-organ candidates would need to align with kidney-pancreas or simultaneous liver-kidney policies.

The Committee ultimately decided not to move forward with policy requirements to address the examples shown above. The various multi-organ scenarios discussed by the Committee outlined the challenges in developing an equitable multi-organ policy that provides clear rules for OPOs. The Committee acknowledges that this proposal is an important step forward in MOT policy, but does not address all of multi-organ combinations. The Committee is committed to working with stakeholders across the community to continue to address multi-organ allocation policies. The next phase of this effort will address other multi-organ combinations, with eligibility criteria for heart-kidney identified as the next step.

Additional Policy Changes

As the OPTN moves forward with future multi-organ policy changes, it might be beneficial to the transplant community to consolidate multi-organ policies into one location. Feedback collected during the public comment period indicated general support for this consolidation. Therefore, as a first step, the Committee proposes several non-substantive policy modifications.

Policy 5.10: Allocation of Multi-Organ Combinations currently includes the following sections:

- *Policy 5.10.A: Allocation of Heart-Lungs*
- *Policy 5.10.B: Allocation of Liver-Kidneys*
- *Policy 5.10.C: Other Multi-Organ Combinations*.

The first two sections provide references to heart-lung and liver-kidney policies and do not contain substantive policy requirements. The Committee proposes two new policy sections, *5.10.C: Allocation of Kidney-Pancreas* and *5.10.D: Allocation of Liver-Intestines* that will reference kidney-pancreas and liver-intestine policies and serve as placeholders for future consolidation of multi-organ policies. Below is the proposed structure for *Policy 5.10: Allocation of Multi-Organ Committee*:

5.10: Allocation of Multi-Organ Combinations

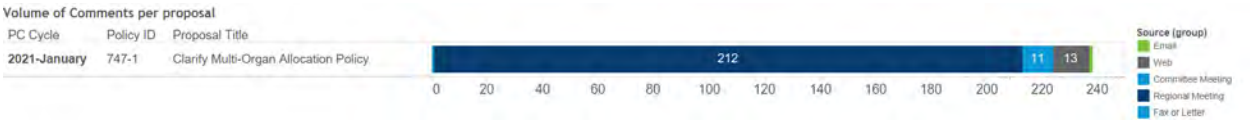
- *5.10.A: Allocation of Heart-Lungs*
- *5.10.B: Allocation of Liver Kidneys*
- *5.10.C: Allocation of Kidney-Pancreas*
- *5.10.D: Allocation of Liver-Intestines*
- *5.10.E: Other Multi-Organ Combinations*

Additional changes include relocating policy language from *Policy 9.9: Liver-Kidney Allocation* to kidney policy. The rationale for this change is that the policy language focuses on kidney allocation as part of multi-organ combinations. This change will not affect liver-kidney allocation policy.

Public Comment Sentiment

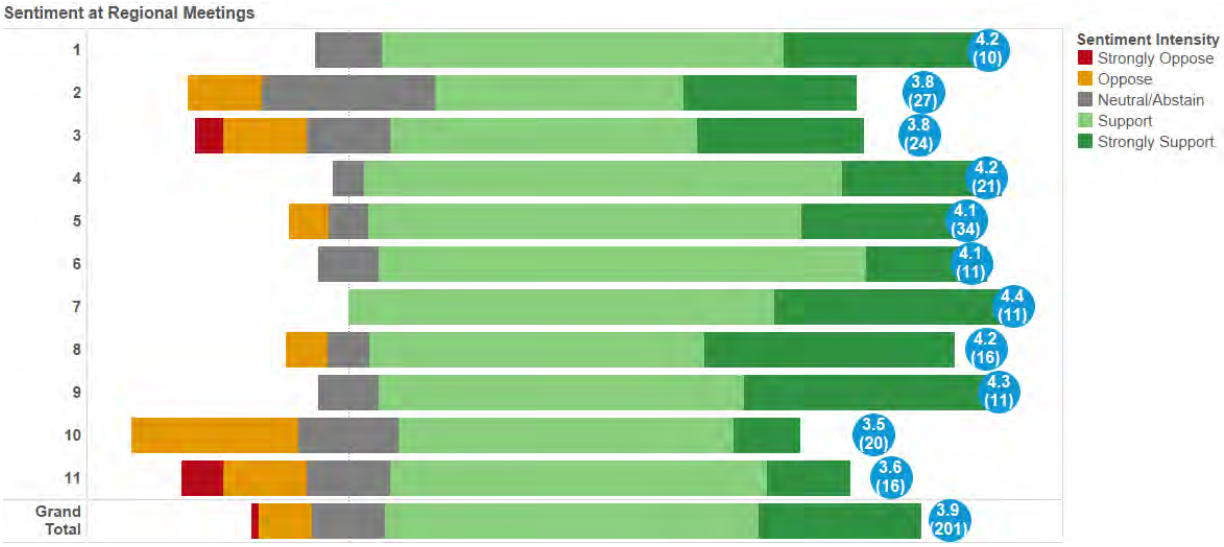
OPO Committee leadership presented the proposal to 12 other OPTN Committees and produced a recorded webinar presenting the proposal, which was posted to the OPTN website. The 11 OPO Committee regional representatives similarly presented this proposal to their respective regions. 5 professional organizations and numerous transplant programs, OPOs and OPO representatives, and individuals provided written public comment. The transplant community was generally supportive of the proposal, with the understanding that this is the initial phase in updating and improving multi-organ allocation policy. 81 percent of the sentiment scores collected were supportive or strongly supportive of the proposal. Sentiment is detailed below in **Figures 2-4:**

Figure 2: Volume of Comments, Clarify Multi-Organ Allocation Policy, 2021[22]



The proposal collected sentiment from 238 respondents, including 26 written comments, about 12% percent of responses.

Figure 3: Sentiment at Regional Meetings, Clarify Multi-Organ Allocation Policy, 2021[23]

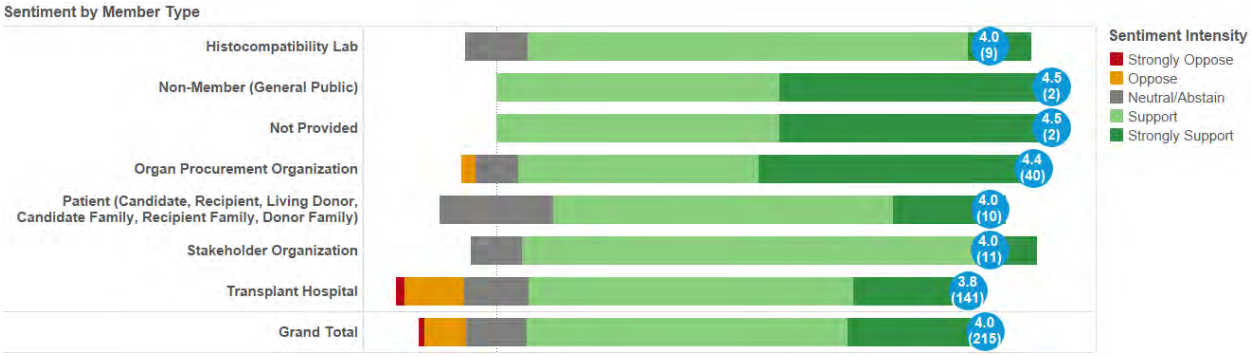


[22] This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for regional meetings only includes attendees at that regional meeting. Region 6 uses the average score for each institution. The circles after each bar indicate the average sentiment score and the number of participants in is in the parentheses.

[23] This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for regional meetings only includes attendees at that regional meeting. Region 6 uses the average score for each institution. The circles after each bar indicate the average sentiment score and the number of participants in is in the parentheses.

The proposal was presented at 11 regional meetings, in which 212 sentiment scores were recorded. 80 percent of regional sentiment recorded was supportive or strongly supportive.

Figure 4: Sentiment by Member Type, Clarify Multi-Organ Allocation Policy, 2021[24]



Sentiment was provided by a wide range of members, with the vast majority of responses submitted by transplant hospitals and OPOs.

The feedback collected covered many topics, including eligibility criteria and "safety net" second organ priority, impact on single-organ candidates, pediatric priority, heart and lung criteria, and modelling and monitoring with the 500 nautical mile expansion. There was considerable support for eligibility criteria and safety net kidney or liver in future multi-organ allocation policy. The community was generally supportive of the proposed heart and lung criteria. There was significant support to expand these criteria to include lung candidates under 12 years old, as well as pediatric heart status 2 candidates. Further concern was also demonstrated for heart status 4 multi-organ patients, including Fontan physiology patients. Community feedback also reflected concern for single-organ kidney and liver candidates, particularly high MELD and medically urgent liver candidates and highly sensitized, pediatric, and low EPTS kidney patients. Similarly, there was demonstrable interest in the community for modelling and monitoring of the effects of the 500 NM threshold on kidney and liver access. Overall, the community was generally supportive of the proposal, and encouraging of future work towards more equitable and efficient multi-organ allocation policy. The OPO Committee reviewed and discussed the community feedback, and approved the expansion of heart and lung criteria to include pediatric heart status 2 candidates and lung candidates less than 12 years old as the only post-public comment changes.

Next Steps

As stated in the previous sections, this proposal by the Committee is the first step in a long-term effort and strategic policy priority by the Policy Oversight Committee (POC). The OPO Committee will collaborate with clinical and organ-specific committees in the coming efforts to further address other multi-organ OPTN policies to ensure efficient and equitable access to transplant for multi-organ and single-organ candidates.

[24] Ibid.

NOTA and Final Rule Analysis

The OPO Committee submits this proposal under the authority of the OPTN Final Rule, which states "The OPTN Board of Directors shall be responsible for developing….policies for the equitable allocation of cadaveric organs"[25] and "shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate."[26] This proposal impacts allocation as it creates rules for how an OPO should allocate heart-kidney, heart-liver, lung-kidney, and lung-liver multi-organ combinations.

The Final Rule 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."[27] This proposal:

- **Is based on sound medical judgment:**[28] The Committee proposes this change based on the medical judgment of OPO professionals, transplant surgeons, and members of eleven stakeholder committees in deriving the proposed changes. The Committee's recommendations were informed by reviews of OPTN data and peer review literature.
- **Is designed to avoid wasting organs:**[29] The Committee believes this proposal will decrease the number of organs recovered but not transplanted, which maximizes the gift of organ donation by using each donated organ to its full potential. This proposal seeks to avoid organ loss by ensuring clear rules for allocating multi-organ combinations while also allowing OPOs the flexibility to make discussions related to organ placement.
- **Is designed to avoid futile transplants:**[30] This proposal establishes medical criteria providing appropriate access to the second organ for heart and lung potential recipients, and so seeks to avoid and reduce futile transplants occurring under mandatory sharing requirements of the current policy language.
- **Is designed to promote patient access to transplantation:**[31] This proposal establishes clear rules for when to offer the second organ with the heart or lung, which will reduce inconsistent application created by the current policy language. The proposal provides access to the second organ for sicker heart and lung potential recipients, with consideration for the unique challenges of pediatric populations.
- **Is designed to promote the efficient management of organ placement:**[32] This proposal provides clear rules for when to offer the second organ with the heart or lung, which will ensure that OPOs more efficiently allocate these multi-organ combinations.

[25] 42 CFR §121.4(a)(1) and §121.8(a)
[26] 42 CFR §121.8(a)(4)
[27] 42 CFR §121.8(a)(1)-(8)
[28] 42 CFR §121.8(a)(1)
[29] 42 CFR §121.8(a)(5)
[30] 42 CFR §121.8(a)(5)
[31] 42 CFR §121.8(a)(5)
[32] 42 CFR §121.8(a)(5)

This proposal also preserves the ability of a transplant program to decline and offer or not use the organ for a potential recipient,[33] and it is specific to various combinations of organ types, as it outlines clearer rules for allocating certain multi-organ combination types.[34]

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:

- This proposal is not based on a candidate's place of residence or place of listing

The Final Rule also requires the OPTN to "consider whether to adopt transition procedures" whenever organ allocation policies are revised.[35] The Committee did not identify any populations may be treated "less favorably than they would have been treated under the previous policies" if these proposed policies are approved by the Board of Directors, and does not recommend any particular transition procedures.

Alignment with OPTN Strategic Plan[36]

Improve equity in access to transplants:
This proposal intends to improve equity in access to transplants by addressing equity for multi-organ candidates. The proposed policy change will improve consistency and transparency in multi-organ allocation by clarifying when an OPO is required to offer the liver or a kidney, if available, from the same donor when allocating the heart or lung. This proposal also improves consistency by specifying the "second organ" currently mentioned in OPTN *Policy 5.10.C,* and bringing multi-organ policy distance thresholds into alignment with current thoracic allocation policies.

Implementation Considerations

Member and OPTN Operations

Operations affecting Organ Procurement Organizations

OPOs will continue allocating donor organs, including hearts and lungs, according to the appropriate match runs. OPO staff will need to be aware of the new requirements for when the liver or kidney is offered to a heart or lung potential transplant recipient.

Operations affecting Transplant Hospitals

Transplant programs may be impacted by the change to 500NM for heart and lung candidates who need either a liver or kidney. In practice, transplant programs receiving offers for both organs should evaluate the logistics and work with the host OPO to facilitate placement.

[33] 42 CFR §121.8(a)(3)
[34] 42 CFR §121.8(a)(4)
[35] 42 CFR §121.8(d)
[36] For more information on the goals of the OPTN Strategic Plan, visit https://optn.transplant.hrsa.gov/governance/strategic-plan/.

Operations affecting Histocompatibility Laboratories

This proposal is not anticipated to affect the operations of histocompatibility laboratories

Operations affecting the OPTN

This proposal will require implementation in UNet[SM] including a visual indicator on the organ match runs to display candidates who meet the requirements for multi-organ allocation. This is meant to aid the OPO in determining if multi-organ allocation requirements have been met prior to offering the second required organ.

Potential Fiscal Impact of Proposal

Projected Impact on OPOs

Policy and implementation changes associated with this proposal adds efficiency and consistency across systems because it creates a better organ matching system. Current workflow varies at each OPO for multi-organ allocation, but minimal effort is needed to adjust and create these efficiencies.

Projected Impact on Transplant Hospitals

There is no or minimal expected fiscal impact for transplant hospitals.

Projected Impact on Histocompatibility Laboratories

There is no expected fiscal impact for histocompatibility laboratories.

Projected Impact on the OPTN

Policy and Community Relations (PCR) hosted a workgroup to develop proposed clarifications to multi-organ allocation policy. PCR staff worked with cross-department UNOS staff to prepare the proposal for public comment, and incorporate changes to the proposal based on the Committee's decisions following public comment.

A Medium IT implementation effort, estimated at 648 hours, includes updates to four different allocations across two organs, heart and lung, which includes heart/lung matches. This will require adding a new column to the heart, lung, and heart-lung match runs and new logic to determine whether a candidate has a waitlist registration for either a liver or a kidney, and whether they meet the policy requirements to be offered the second organ. These changes will require testing for all organs to ensure that allocation functions as described in policy.

Research anticipates a Very Small effort in routine monitoring, and the Organ Center anticipates a Very Small effort to answer member questions related to the allocation changes.

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."[37]

The proposed language will not change the routine allocation monitoring of OPTN members. The OPTN will continue to review all deceased donor match runs that result in a transplanted organ and will continue to investigate potential policy violations.

Policy Evaluation

The Final Rule requires that allocation policies "be reviewed periodically and revised as appropriate."[38] This policy will be formally evaluated approximately 6 months, 1 year, and 2 years post-implementation. The following metrics, and any others subsequently requested by the Committee, will be evaluated as data become available (appropriate lags will be applied, per typical OPTN conventions, to account for time delay in institutions reporting data to UNet℠) and compared to an appropriate pre-implementation cohort.

For heart-liver, heart-kidney, lung-liver, and lung-kidney:

- Number of multi-organ transplants
    - Stratify by required vs permissible share
    - Stratify by individual organ medical urgency
    - Stratify by adult vs pediatric
    - Stratify by distance from donor hospital to transplant center
    - By OPTN Region
- Number of deaths on the waiting list for multi-organ candidates
    - Stratify by individual organ medical urgency
    - Stratify by adult vs pediatric
    - By OPTN Region
- Waitlist volumes for multi-organ candidates
    - Stratify by individual organ medical urgency
    - Stratify by adult vs pediatric
    - By OPTN Region

[37] 42 CFR §121.8(a)(7)
[38] 42 CFR §121.8(a)(6)

Conclusion

This proposal addresses the initial phase of the POC strategic policy priority to address multi-organ policies by clarifying OPTN *Policy 5.10.C: Other Multi-Organ Combinations*. The OPO Committee proposes criteria for when OPOs are required to offer the liver or kidney, if available, from the same donor. For heart candidates, the criteria will include adult status 1, 2, and 3 and pediatric 1A and 1B. For lung candidates, the criteria will include candidates with a lung allocation score of greater than or equal to 35. After feedback collected during public comment, the OPO Committee is expanding these criteria to include heart pediatric status 2 candidates and all lung candidates less than 12 years old. Additionally, the proposed distance for this mandatory offer will be increased from the current 250 nautical mile circle for heart and lung to a 500 nautical mile circle to better align with thoracic allocation policies.

The Committee is also proposing these policy changes as the initial step towards consolidating multi-organ allocation policies within OPTN Policy. The Committee received general support for this consolidation throughout the public comment period.

The Committee proposes these policy changes to promote efficient and equitable allocation for these multi-organ combinations. This proposal is a continuation of previous efforts and builds a foundation for the continued work within the strategic policy priority to address multi-organ allocation policies.

Policy Language

RESOLVED, that the creation of Policies *5.10.C: Allocation of Kidney-Pancreas, 5.10.D: Allocation of Liver-Intestines, 8.7.C: Kidney Allocation in Multi-Organ Combinations*, as well as changes to Policies *5.10.C: Other Multi-Organ Combinations* and *9.9: Liver-Kidney Allocation*, as set forth below, are hereby approved, effective pending implementation and notice to OPTN members.

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.

5.10 Allocation of Multi-Organ Combinations

5.10.C Allocation of Kidney-Pancreas

Kidney-pancreas combinations are allocated according to *Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets.*

5.10.D Allocation of Liver-Intestines

Liver-intestine combinations are allocated according to *Policy 9: Allocation of Livers and Liver-Intestines.*

5.10.E Other Multi-Organ Combinations

~~When multi-organ candidates are registered on the heart, lung, or liver waiting list, the second required organ will be allocated to the multi-organ candidate from the same donor according to *Table 5-4.*~~

~~**Table 5-4: Allocation of Multi-Organ Combinations**~~

~~**Organ**~~	~~**Candidate is registered at a transplant hospital that is at or within the following this distance of the donor hospital**~~
~~Heart~~	~~250NM~~
~~Liver~~	~~150NM~~
~~Lung~~	~~250NM~~

~~If the multi-organ candidate is on a waiting list outside the geographical areas listed above, it is permissible to allocate the second organ to the multi-organ candidate receiving the first organ.~~

When an OPO is offering a heart or lung, and a liver or kidney is also available from the same deceased donor, PTRs who meet the criteria in *Table 5-4* must be offered the second organ.

Table 5-4 Second Organ for Heart or Lung PTRs

If the OPO is offering the following organ:	And a PTR is also registered for one of the following organs:	The OPO must offer the second organ if the PTR is registered at a transplant hospital at or within 500 NM of the donor hospital and meets the following criteria:
Heart	Liver or Kidney	Heart Adult Status 1, 2, 3 or any active pediatric status
Lung	Liver or Kidney	Lung allocation score of greater than or equal to 35 or candidates less than 12 years old

When the OPO is offering a heart or lung and two PTRs meet the criteria in *Table 5-4*, the OPO has the discretion to offer the second organ to either PTR.

It is permissible for the OPO to offer the second organ to other multi-organ PTRs that do not meet the criteria above.

8.7.C Kidney Allocation in Multi-Organ Combinations

If a host OPO procures a kidney along with other organs, the host OPO must first offer the kidney according to one of the following policies before allocating the kidney to kidney alone candidates according to *Policy 8: Allocation of Kidneys*:

- *Policy 5.10.E: Other Multi-Organ Combinations*
- *Policy 9.9: Liver-Kidney Allocation*
- *Policy 11.4.A: Kidney-Pancreas Allocation Order*

9.9 Liver-Kidney Allocation

~~If a host OPO procures a kidney along with other organs, the host OPO must first offer the kidney according to one of the following policies before allocating the kidney to kidney alone candidates according to Policy 8: Allocation of Kidneys:~~

- ~~*Policy 5.10.C: Other Multi-Organ Combinations*~~
- ~~*Policy 9.9: Liver-Kidney Allocation*~~
- ~~*Policy 11.4.A: Kidney-Pancreas Allocation Order*~~

If a host OPO is offering a kidney and a liver 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 who meet eligibility according to *Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation* and are one of the following:

a. Within 150 nautical miles of the donor hospital and have a MELD or PELD of 15 or higher

b. Within 250 nautical miles of the donor hospital and have a MELD or PELD of at least 29
c. Within 250 nautical miles of the donor hospital and status 1A or 1B.

The host OPO may then do either of the following:

a. Offer the kidney and liver to any candidates who meet eligibility in *Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation*.
b. Offer the liver to liver alone candidates according to *Policy 9: Allocation of Livers and Liver-Intestines* and offer the kidney to kidney alone candidates according to *Policy 8: Allocation of Kidneys*.

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