OPTN

Public Comment Proposal

Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation

OPTN Ad Hoc Multi-Organ Transplantation Committee

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Executive Summary

Policy changes approved by the Organ Procurement and Transplantation Network (OPTN) Board of Directors in June 2021[1] established the criteria by which a kidney must be allocated to a candidate along with a heart or lung, based on the candidate's medical urgency for the heart or lung and the candidate's distance from the donor hospital. However, the policy changes did not set any requirements for the candidate's kidney function before they can receive the kidney.

The Ad Hoc Multi-Organ Transplantation (MOT) Committee (hereafter, the Committee) proposes establishing eligibility criteria and safety net policies for heart-kidney and lung-kidney allocation. This proposal would establish eligibility criteria for heart-kidney and lung-kidney candidates based on renal function in order to restrict required offers to candidates with clinical justification to receive the kidney along with the heart or lung, thereby promoting access to transplant for kidney-alone candidates. Additionally, this proposal establishes criteria for prioritizing recipients of heart-alone and lung-alone transplants on the kidney waiting list if the recipients also meet medical and temporal criteria for a kidney transplant following their heart or lung transplant. The prioritization is referred to as a "safety net" for heart- and lung-alone recipients who are also registered for a kidney. Taken together, the proposed eligibility criteria and safety net prioritization are intended to improve equity in transplant opportunities for multi-organ and single-organ candidates. This proposal does not change existing eligibility criteria and safety net priority for simultaneous liver-kidney (SLK) transplantation.

[1] OPTN Board of Directors Executive Summary, June 14, 2021, OPTN, accessed August 3, 2021, https://optn.transplant.hrsa.gov/media/4708/20210614_board-of-directors_executive-summary.pdf.

Background

The equitable and efficient allocation of multi-organ transplantation relative to single-organ transplantation (SOT) remains an active area of OPTN policy discussion. Broadly, members of the transplant community have expressed concerns about the perceived differences in how organs are allocated for multi-organ transplants. Likewise, the transplant community has questions regarding equity in access to organs for SOT candidates relative to MOT candidates.

OPTN policies have historically required organ procurement organizations (OPOs) to allocate multiple organs from the same donor to MOT candidates meeting certain criteria prior to allocating individual organs to SOT candidates. These general policies on multi-organ allocation have been periodically updated to reflect changes in single-organ allocation policies, including for recent proposals that removed donation service area (DSA) and regions from heart, kidney, liver, lung, pancreas, and vascularized composite allograft allocation policies.[2,3]

In 2017, the OPTN implemented more detailed policy requirements specific to liver-kidney allocation.[4] These policy changes were prompted by concerns about the increasing volume of SLK transplants following a shift in liver allocation policy that gave greater priority for liver-kidney transplant to sicker liver candidates.[5] The policies established eligibility criteria for SLK allocation (OPTN *Policy 9.9: Liver-Kidney Allocation*) and a safety net for liver-alone transplant recipients who also need a kidney transplant (OPTN *Policy 8.5G: Prioritization for Liver Recipients on the Kidney Waiting List*).

Eligibility criteria are qualifying conditions for a candidate to receive a second organ (in this case, a kidney) simultaneously with another organ (a liver, in the case of SLK). Some patients experiencing non-renal organ failure as well as impaired kidney function may recover native kidney function after receiving a single-organ transplant,[6,7] whereas some other patients must undergo multi-organ transplant to achieve a successful outcome. The intent of the eligibility criteria is to ensure that organs are allocated to MOT candidates who have sufficient clinical justification to receive more than one organ at the same time.

Safety net requirements prioritize recipients of a single-organ transplant who qualify for a second organ (e.g. a kidney) shortly after the initial transplant. The intent of safety net policies is to protect access to transplant for patients who do not recover function in a second organ after a single-organ transplant.

In this way, policies addressing eligibility criteria and safety net priority work hand-in-hand to promote access to transplantation for SOT candidates and MOT candidates meeting established requirements, while also protecting access to transplant for patients who receive a single-organ transplant but still need an additional organ transplant. To date, the OPTN has established eligibility criteria and a safety net policy only for liver-kidney allocation.

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[2] "Eliminate the Use of DSAs in Thoracic Distribution," Briefing Paper, OPTN, accessed November 7, 2021, https://optn.transplant.hrsa.gov/media/2994/thoracic_boardreport_201906.pdf.

[3] "Liver and Intestine Distribution Using Distance from Donor Hospital," Briefing Paper, OPTN, accessed November 7, 2021, https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf.

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

[5] 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.

[6] J. Levitsky, T. Baker, S. N. Ahya, et al., "Outcomes and Native Renal Recovery Following Simultaneous Liver-Kidney Transplantation," *American Journal of Transplantation* 12 (2012): 2949-2957, doi: 10.1111/j.1600-6143.2012.04182.x.

[7] Jean M. Francis, Matthew R. Palmer, Kevin Donohoe, et al., "Evaluation of Native Kidney Recovery After Simultaneous Liver-Kidney Transplantation," *Transplantation* 93, no. 5 (March 2012): 530-535, DOI: 10.1097/TP.0b013e3182449161.

In 2019, the OPTN Policy Oversight Committee (POC) identified multi-organ allocation as a strategic policy priority, which was approved by the OPTN Executive Committee.[8] As part of this process, the POC and the Executive Committee approved a multi-pronged approach to MOT that included a gap analysis and updates to general multi-organ policy, followed by policy development regarding specific MOT combinations (e.g. heart-kidney and lung-kidney). In the same year, the OPTN Ethics Committee released the white paper, *Ethical Implications of Multi-Organ Transplants.*[9] The paper noted the following key themes:

- The system for allocation of organs for MOT candidates should be based on the ethical principles of equity and utility, be transparent, and be consistent across the different organ combinations unless there is an ethical justification for a different system
- MOT allocation could have the potential adverse effects of redirecting high-quality organs that are consequently unavailable to SOT candidates
- Allocation policies should prioritize MOT candidates who have medical urgency in both organs, but generally should not prioritize MOT candidates who do not have medical urgency in one organ
- Allocation policies should not disadvantage patients who undergo SOT instead of MOT when the second organ subsequently fails, and when the need for a simultaneous second organ transplant is questionable

In June 2021, the OPTN Board of Directors (BOD) approved updates to general multi-organ policy as proposed by the OPTN OPO Committee.[10] A primary objective of the changes approved by the OPTN Board of Directors in June 2021 was to provide OPOs with clearer directions when offering multi-organ combinations.[11,12] The policy modifications established the circumstances by which a kidney must be allocated to a candidate along with a heart or lung based on the candidate's medical urgency for the heart or lung. The updates also established a distance requirement from the donor hospital. Furthermore, the changes laid the groundwork for creating an ad hoc MOT Committee to continue developing eligibility criteria and safety net policies for other MOT combinations similar to those in place for SLK.[13]

During the public comment period, feedback on the OPO Committee's proposal, *Clarify Multi-Organ Allocation Policy*,[14] raised concerns about perceived inequities related to MOT allocation, which include:

[8] Executive Committee Meeting Summary, October 8, 2019, OPTN, accessed March 29, 2021, https://optn.transplant.hrsa.gov/media/3615/20191008_exec_comm_summary.pdf.
[9] "Ethical Implications of Multi-Organ Transplants," Briefing Paper, OPTN, accessed March 29, 2021, https://optn.transplant.hrsa.gov/media/2989/ethics_boardreport_201906.pdf.
[10] "Clarify Multi-Organ Allocation Policy," OPTN Organ Procurement Organization Committee, Notice of OPTN Policy Changes, June 2021, https://optn.transplant.hrsa.gov/media/4698/clarify_multi-organ_june_2021_policy_notice.pdf (accessed November 7, 2021).
[11] OPTN Board of Directors Executive Summary, June 14, 2021, OPTN, accessed August 3, 2021, https://optn.transplant.hrsa.gov/media/4708/20210614_board-of-directors_executive-summary.pdf.
[12] "Clarify Multi-Organ Allocation Policy," Briefing Paper, OPTN, accessed August 3, 2021, https://optn.transplant.hrsa.gov/media/4634/briefing-paper_june-2021_clarify-multi-organ-policy_draft.pdf.
[13] Xingxing S. Chen, Kiran K. Khush, Alexander Wiseman, et al., "To kidney or not to kidney: Applying lessons learned from the simultaneous liver-kidney transplant policy to simultaneous heart-kidney transplantation," *Clinical Transplantation* 34 (2020): e13878, https://doi.org/10.1111/ctr.13878.
[14] "Clarify Multi-Organ Allocation Policy," Public Comment Web Page, OPTN, accessed March 29, 2021, https://optn.transplant.hrsa.gov/governance/public-comment/clarify-multi-organ-allocation-policy/.

- Lack of medical eligibility requirements for any kidney MOT allocation policy beyond what is in place for SLK allocation[15,16,17,18]
- Increase in volume of heart-kidney transplants[19,20,21] following the 2018 implementation of heart allocation policies that gave more priority to sicker candidates[22,23]
- Imbalance between kidney SOT versus kidney MOT allocation (including SLK)[24]
- Prioritization of kidney MOT candidates over pediatric kidney candidates for access to low Kidney Donor Profile Index (KDPI) kidneys (kidneys with lower expected risk of graft failure)[25,26]

The OPO Committee acknowledged the issues raised at the time. However, the OPO Committee pointed out that theirs was the first step in a larger effort to better align multi-organ allocation policies. The proposal's intent was to provide clearer rules for OPOs for multi-organ allocation while allowing OPOs the discretion to determine the best approach to placing organs, even if the multi-organ candidates do not meet the criteria in the proposal.[27] Specifically, the proposal clarifies when an OPO should offer a liver or a kidney along with a heart or lung.

During development of the present proposal, the MOT Committee considered the public comment feedback associated with the OPO Committee's proposal regarding the impact of allocating kidneys to multi-organ candidates on kidney-alone candidates.[28] As a result, the MOT Committee sought to balance the two by providing further clarification to OPOs concerning when to offer kidneys as part of multi-organ transplants involving heart and lungs.

Ad Hoc Committee Established to Address Multi-Organ Allocation Policy

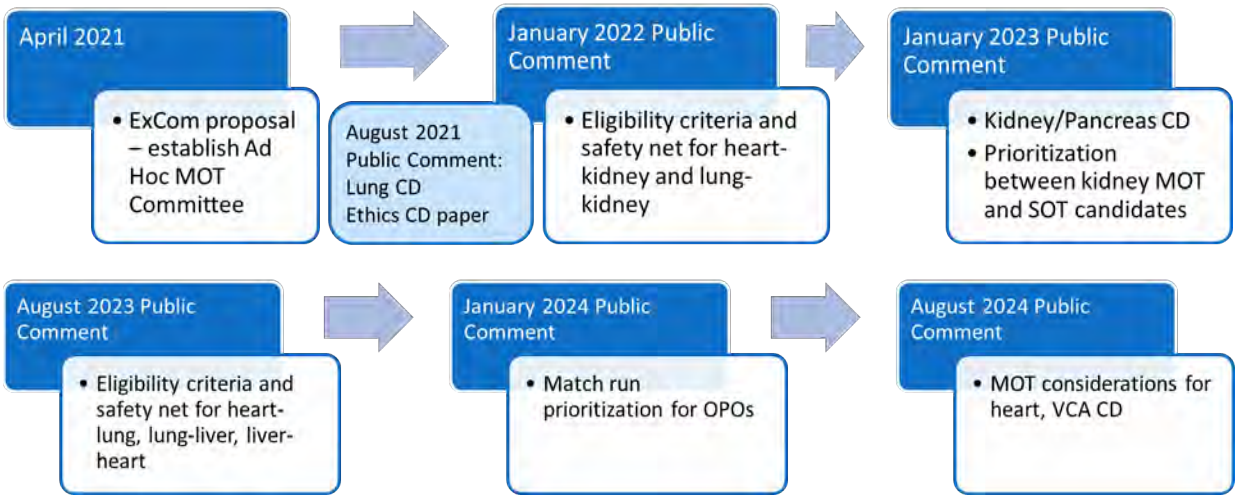
In April 2021, the OPTN Executive Committee created the OPTN Ad Hoc Multi-Organ Transplantation Committee[29] and charged it with developing allocation policies addressing multiple organ groups and the practice of multi-organ allocation.[30] Additionally, the Committee must ensure that proposed multi-

[15] Ibid.
[16] Policy Oversight Committee Meeting Summary, October 14, 2020, OPTN, accessed March 29, 2021, https://optn.transplant.hrsa.gov/media/4159/20201014_poc_meeting-summary.pdf.
[17] Policy Oversight Committee Meeting Summary, December 9, 2020, OPTN, accessed January 24, 2022, https://optn.transplant.hrsa.gov/media/4294/20201209_poc_meeting-summary.pdf
[18] Kidney & Pancreas Transplantation Committee Continuous Distribution Workgroup Meeting Summary, January 15, 2021. OPTN, accessed March 29, 2021, https://optn.transplant.hrsa.gov/media/4410/20210115_kidney-pancreas-continuous-distribution-wg_meeting-summary.pdf.
[19] Ibid.
[20] Kidney & Pancreas Transplantation Committee Continuous Distribution Workgroup Meeting Summary, January 15, 2021, OPTN.
[21] Maryl R. Johnson, "Simultaneous heart-kidney transplant: Working together to define when one organ is not enough," *American Journal of Transplantation* (2021): 1-2, https://doi.org/10.1111/ajt.16564.
[22] Ad Hoc Multi-Organ Committee Meeting Summary, June 21, 2021, OPTN, accessed August 3, 2021, https://optn.transplant.hrsa.gov/media/4713/20210621_mot_meeting-summary_final.pdf.
[23] "One-Year Monitoring of Heart Allocation Proposal to Modify the Heart Allocation System," Descriptive Data Request, February 20, 2020, OPTN, accessed August 3, 2021, https://optn.transplant.hrsa.gov/media/3701/data_report_thoracic_committee_heart_subcommittee_20200227_rpt1_revised_508_compliant.pdf.
[24] Policy Oversight Committee Meeting Summary, April 23, 2020, OPTN, accessed March 29, 2021, https://optn.transplant.hrsa.gov/media/3796/20200423_poc_meeting-summary.pdf.
[25] Policy Oversight Committee Meeting Summary, May 20, 2020, OPTN, Accessed March 29, 2021, https://optn.transplant.hrsa.gov/media/3843/20200520_poc_meeting-summary.pdf.
[26] Policy Oversight Committee Meeting Summary, December 9, 2020.
[27] "Clarify Multi-Organ Allocation Policy," Briefing Paper, OPTN, https://optn.transplant.hrsa.gov/media/4634/briefing-paper_june-2021_clarify-multi-organ-policy_draft.pdf (accessed December 3, 2021), p. 8.
[28] "Clarify Multi-Organ Allocation Policy," Briefing Paper, OPTN, https://optn.transplant.hrsa.gov/media/4634/briefing-paper_june-2021_clarify-multi-organ-policy_draft.pdf (accessed December 3, 2021), p. 8.
[29] OPTN Executive Committee Meeting Summary, OPTN, April 26, 2021, accessed August 3, 2021, https://optn.transplant.hrsa.gov/media/4665/20210426_executive_committee_summary.pdf.
[30] "Ad Hoc Multi-Organ Transplantation Committee," OPTN, accessed August 3, 2021,

organ policies align with the OPTN Final Rule and the planned transition of each organ allocation system to a continuous distribution (CD) framework.[31] The Committee includes representatives from each organ-specific committee and other stakeholder committees, including the Ethics, Minority Affairs, OPO, Pediatrics, and Patient Affairs Committees, to facilitate inclusive policy development on multi-organ allocation.

This proposal is the Committee's first step in what is intended to be a larger portfolio of MOT policy development, as outlined in **Figure 1**.

Figure 1. Proposed Project Map for Ad Hoc Multi-Organ Transplantation Committee[32]



As the OPTN Kidney and Pancreas Transplantation Committees are currently working on a proposal to transition the kidney and pancreas allocation systems to a continuous distribution framework,[33] the Committee plans to focus its initial efforts on multi-organ allocation policies impacting kidneys. This way, any BOD-approved changes to kidney multi-organ allocation policies can be implemented in coordination with other BOD-approved changes to kidney allocation. The Committee based its decision in part because kidneys are also the most commonly used organs in multi-organ transplants, as approximately 92% of all multi-organ transplants performed in the U.S. in recent years included a kidney, making up 10-11% of all kidney transplants.[34]

Changes in the Number of Kidneys Used in Multi-Organ Transplants

OPTN data show that multi-organ transplants involving kidneys have increased in volume in recent years, but at a lower rate than the increase in kidney transplants overall**. Figure 2** identifies the number of pancreas-kidney, liver-kidney, heart-kidney, and lung-kidney transplants beginning in 2016 through

https://optn.transplant.hrsa.gov/members/committees/ad-hoc-multi-organ-committee/.

[31] Each organ-specific committee will perform an analysis and assessment in order to determine whether a continuous distribution allocation framework will be an improvement over the existing allocation framework.

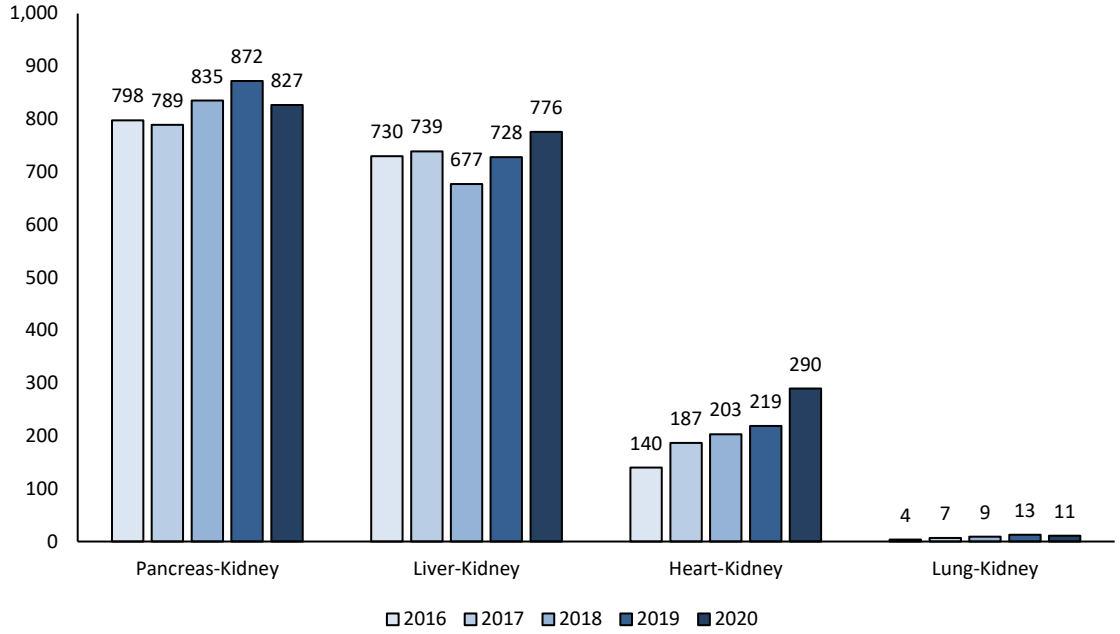
[32] ExCom: Executive Committee; "Lung CD" refers to the OPTN Lung Transplantation Committee's Board briefing paper *Establish Continuous Distribution of Lungs*; "Ethics CD" refers to the OPTN Ethics Committee's white paper *Ethical Considerations of Continuous Distribution in Organ Allocation;* VCA: vascularized composite allograft

[33] "Update on Continuous Distribution of Kidneys and Pancreata," Concept Paper, OPTN, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/update-on-continuous-distribution-of-kidneys-and-pancreata/ (accessed December 12, 2021), and "Update on Continuous Distribution of Kidneys and Pancreata," Request for Feedback, OPTN, January – March 2021, public comment period.

[34] Based on OPTN data for 2018-2020.

2020.[35] The number of transplants increased for each of the four multi-organ combinations during that time. Twenty-nine more pancreas-kidney transplants were performed in 2020 compared to 2016, and liver-kidney transplants increased by 46 during the timeframe.

Figure 2: Number of Multi-Organ Transplants Involving Kidneys, 2016 - 2020



Source: United States Department of Health and Human Services, Organ Procurement and Transplantation Network website, https://optn.transplant.hrsa.gov/data/view-data-reports/build-advanced/, (accessed November 7, 2021).

Figure 2 also demonstrates that the number of heart-kidney transplants have increased in volume. As shown, heart-kidney transplants increased from 140 in 2016 to 290 in 2020, more than doubling during the timeframe. An average annual growth rate can be calculated based on the volumes displayed in the figure. Heart-kidney transplants experienced average annual growth of 21 percent. Lung-kidney transplants grew by 33 percent (although the total number of lung-kidney transplants remains small compared to the other combinations).

Heart-Kidney Transplantation

For patients that have heart failure as well as impaired renal function, transplant programs must decide whether these patients should be registered as candidates to receive a heart-alone transplant or a simultaneous heart-kidney transplant (SHK). According to guidelines created by the International Society for Heart and Lung Transplantation (ISHLT), heart-alone transplant is not recommended for patients with an estimated glomerular filtration rate (eGFR) less than 30 mL/min/1.73m^2.[36] Estimated glomerular filtration rate is a measure used to estimate the rate at which the kidneys remove waste products from the blood and helps determine the severity of a patient's kidney disease.[37] However, multi-organ

[35] OPTN data as of May 31, 2021. Data shown do not reflect the total volume of transplants performed in the U.S. in this timeframe.

[36] Mandeep R. Mehra, Charles E. Canter, Margaret M. Hannan, et al., "The 2016 International Society for Heart Lung Transplantation listing criteria for heart transplantation: A 10-year update," *The Journal of Heart and Lung Transplantation* 35, no. 1 (January 2016): 1-23, http://dx.doi.org/10.1016/j.healun.2015.10.023.

[37] Establish OPTN Requirement for Race-Neutral eGFR Calculations, OPTN Minority Affairs and Kidney Transplantation Committees, January 2022,

transplantation may be an option for these patients, and evidence from clinical literature supports SHK in certain patients. In particular, studies show that SHK offers a survival advantage to patients on dialysis and patients with low GFR prior to transplant, relative to patients on dialysis and patients with low GFR who receive a heart-alone transplant.[38,39] Heart-kidney transplant recipients have also shown improved five-year survival compared to heart-alone recipients with renal impairment.[40] This evidence suggests that it may be appropriate to prioritize certain patients for SHK through eligibility criteria.

Patient Survival for Recipients of Kidney-After-Heart Transplant

Patients who receive a heart-alone transplant and have impaired renal function may be considered candidates for a subsequent kidney transplant (kidney-after-heart transplant). Such patients tend to have a greater risk of dying while waiting for a kidney compared to kidney candidates with no previous transplant,[41] particularly those patients with advanced chronic kidney disease.[42] When comparing the risk of death following kidney transplantation versus the risk of death on the waiting list, kidney transplantation offered a survival advantage to patients with a previous heart transplant.[43,44] This evidence suggests that it may be appropriate to establish a safety net to "catch" patients who do not meet eligibility criteria for SHK but require a kidney transplant shortly after heart transplant.

Graft Survival

As allocation policies "shall be designed to avoid wasting organs" and "to avoid futile transplants,"[45] graft survival should be considered as well as patient survival when considering how to prioritize multi-organ candidates relative to single-organ candidates. Evidence on graft survival for SHK recipients is mixed. One study found superior four-year graft survival for SHK recipients on dialysis prior to transplantation relative to heart-alone recipients.[46] However, another study found that SHK recipients on dialysis pre-transplant had higher rates of delayed kidney graft function, which is a risk factor for shortened kidney graft survival.[47] Previous OPTN analysis found that early kidney graft survival is worse in SHK recipients compared to kidney-alone recipients, but the graft survival rates between the two

https://bodandcommittees.unos.org/committeeprojects/_layouts/15/WopiFrame.aspx?sourcedoc=/committeeprojects/Policy%20and%20Bylaw%20Language%20Drafts/2022January_EstablisheGFRReq_Proposal.docx&action=default (accessed December 6, 2021), p. 3.

[38] Tara Karamlou, Karl Welke, D. Michal McMullan, et al., "Combined heart-kidney transplant improves post-transplant survival compared with isolated heart transplant in recipiends 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.

[39] Arman Kilic, Joshua C. Grimm, Glenn J.R. Whitman, et al., "The Survival Benefit of Simultaneous Heart-Kidney Transplantation Extends Beyond Dialysis-Dependent Patients," *The Annals of Thoracic Surgery* 99, no. 4 (April 2015): 1321-1327, https://doi.org/10.1016/j.athoracsur.2014.09.026.

[40] Cecillia Lui, Charles D. Fraser III, Xun Zhou, et al., "Increased Use of Multiorgan Transplantation in Heart Transplantation: Only Time Will Tell," *The Annals of Thoracic Surgery* 110 (2020): 1308-1315, https://doi.org/10.1016/j.athoracsur.2019.12.081.

[41] Titte R. Srinivas, Brian R. Stephany, Marie Budev, et al., "An Emerging Population: Kidney Transplant Candidates Who Are Placed on the Waiting List After Liver, Heart, and Lung Transplantation," *Clinical Journal of the American Society of Nephrology* 5, no. 10 (October 2010): 1881-1886, https://doi.org/10.2215/CJN.02950410.

[42] J. R. Cassuto, P. P. Reese, S. Sonnad, et al., "Wait List Death and Survival Benefit of Kidney Transplantation Among Nonrenal Transplant Recipients," *American Journal of Transplantation* 10 (2010): 2502-2511, doi: 10.1111/j.1600-6143.2010.03292.x.

[43] B.E. Lonze, D.S. Warren, Z. A. Stewart, et al., "Kidney Transplantation in Previous Heart or Lung Recipients," *American Journal of Transplantation* 9 (2009): 578-585, doi: 10.1111/j.1600-6143.2008.02540.x.

[44] Cassuto, "Wait List Death," 2510.

[45] 42 CFR §121.8(a)(5)

[46] J. Gill, T. Shah, I. Hristea, et al., "Outcomes of Simultaneous Heart-Kidney Transplant in the US: A Retrospective Analysis Using OPTN/UNOS Data," *American Journal of Transplantation* 9 (2009): 844-852, doi: 10.1111/j.1600-6143.2009.02588.x.

[47] Sandesh Parajuli, Aos S. Karim, Brenda L. Muth, et al., "Risk factors and outcomes for delayed kidney graft function in simultaneous heart and kidney transplant recipients: A UNOS/OPTN database analysis," *American Journal of Transplantation* 21 (2021): 3005-3013, DOI: 10.1111/ajt.16535.

groups seem to converge around three years post-transplant.[48] It appears that SHK transplantation is not futile for certain patients and is particularly beneficial for those on dialysis prior to transplant.

For kidney-after-heart recipients, one study found lower kidney graft survival rates in this population relative to kidney-alone recipients, but this trend was attributable to higher rates of patient death in the kidney-after-heart population.[49] Overall, the same study found that "renal grafts function well and provide survival benefit in [kidney-after-heart] recipients" compared to heart recipients who remained on the kidney waiting list. Heart recipients who received kidney transplants had a median survival of 85.9 months, compared to just 52.7 months for heart recipients who remained on the kidney waiting list, which shows such kidney transplants are not futile.[50] Accordingly, the observed patient survival benefit of kidney-after-heart transplantation relative to remaining on the waitlist may balance concerns about worse graft survival in these patients relative to kidney-alone recipients.

A consensus conference convened in 2019 to discuss heart-kidney transplantation determined that SHK "can improve survival and the quality of life of the patients with severe heart and kidney disease" but noted that "in the setting of organ scarcity, SHK should be considered with respect to both the individual patient's need for the organs in question and the effect of SHK on kidney-alone candidates' access to transplant."[51] Consensus statements developed at the conference suggested clinical criteria for considering patients for SHK and recommended a safety net policy for patients who receive heart-alone transplants but remain on chronic dialysis or with persistently low GFR after transplant.

Lung-Kidney Transplantation

Simultaneous lung-kidney transplantation (SLuK) is much less common than SHK but may be appropriate for certain lung candidates with impaired renal function. International guidelines jointly issued by several stakeholders, including ISHLT, in 1998 referred to renal dysfunction, defined as creatinine clearance of < 50 mg/mL/min, as a contraindication to lung transplantation because of the impact of immunosuppressive drugs on renal function.[52] A 2014 study noted that while subsequent guidelines removed the 50 mg/mL/min creatinine clearance threshold as a contraindication to transplantation,[53] many transplant programs at the time continued using renal function as a contraindication and some programs continued to exclude candidates based on GFR less than 50 mL/min/1.73m^2.[54] The study suggested that this cut-off is reasonable due to adverse outcomes for lung-alone recipients with a GFR below this threshold.[55] These patients may benefit from SLuK, and evidence from clinical literature demonstrates a survival advantage of SLuK for patients on dialysis prior to transplant relative to lung-

[48] "Simultaneous Liver-Kidney Allocation," Briefing Paper, OPTN, June 2016, accessed August 6, 2021, https://optn.transplant.hrsa.gov/media/1871/kidney_briefingpaper_slk_201606.pdf
[49] Lonze, "Kidney Transplantation," 583.
[50] Lonze, "Kidney Transplantation," 583.
[51] Jon Kobashigawa, Darshana M. Dadhania, Maryjane Farr, et al., "Consensus conference on heart-kidney transplantation," *American Journal of Transplantation* 00 (2021): 1-9, DOI: 10.1111/ajt.16512.
[52] Janet R. Maurer, Adaani E. Frost, Marc Estenne, et al., "International Guidelines for the Selection of Lung Transplant Candidates," *Transplantation* 66, no. 7 (1998): 951-956, DOI: 10.1097/00007890-199810150-00033.
[53] Jonathan B. Orens, et al., "International Guidelines for the Selection of Lung Transplant Candidates: 2006 Update—A Consensus Report From the Pulmonary Scientific Council of the International Society for Heart and Lung Transplantation," The Journal of Heart and Lung Transplantation 25, no. 7 (2006): 745–55, https://doi.org/10.1016/j.healun.2006.03.011.
[54] Asishana A. Osho, Anthony W. Castleberry, Laurie D. Snyder, et al., "Assessment of Different Threshold Preoperative Glomerular Filtration Rates as Markers of Outcomes in Lung Transplantation," *The Annals of Thoracic Surgery* 98 (2014): 283-290, http://dx.doi.org/10.1016/j.athoracsur.2014.03.010.
[55] Asishana A. Osho, Anthony W. Castleberry, Laurie D. Snyder, et al., "Assessment of Different Threshold Preoperative Glomerular Filtration Rates as Markers of Outcomes in Lung Transplantation," *The Annals of Thoracic Surgery* 98 (2014): 283-290, http://dx.doi.org/10.1016/j.athoracsur.2014.03.010.

alone recipients who require dialysis after transplant.[56] Additionally, patient survival after SLuK is similar to patient survival after lung-alone transplant, which suggests that SLuK is a feasible option for lung candidates with significant kidney dysfunction.[57]

Patient Survival for Recipients of Kidney-After-Lung Transplant

Patients who receive a lung-alone transplant and have impaired renal function may be considered candidates for a subsequent kidney transplant (kidney-after-lung transplant). Such patients tend to have a greater risk of dying while waiting for a kidney compared to kidney candidates with no previous transplant,[58] particularly those patients with advanced chronic kidney disease.[59] When comparing the risk of death following kidney transplantation versus the risk of death on the waiting list, kidney transplantation proffered a survival advantage to patients with a previous lung transplant.[60,61] This evidence suggests that it may be appropriate to establish a safety net to "catch" patients who do not meet eligibility criteria but require a kidney transplant shortly after lung transplant.

Graft Survival

There is limited evidence on graft survival following SLuK transplant. Studies on graft survival in kidney-after-lung transplant recipients found lower rates of kidney graft survival relative to kidney-alone recipients, but as with kidney-after-heart recipients, the higher graft loss was attributable to higher rates of post-transplant death among kidney-after-lung recipients relative to kidney-alone recipients.[62,63] However, studies also found that there is a clear survival benefit to kidney-after-lung transplantation relative to lung recipients who remain on the kidney waiting list, demonstrating that these transplants are not futile. One study found that lung recipients who received a kidney transplant had a median survival of 72.9 months, compared to 37.1 months for lung recipients who remained on the kidney waiting list.[64] A subsequent study found a similarly significant survival advantage for lung recipients who received a kidney transplant compared to those who remained on the kidney waiting list.[65]

Purpose

Simultaneous heart-kidney transplants have been increasing in recent years, growing from 140 transplants in 2016 to 290 transplants in 2020.[66] The proportion of simultaneous heart-kidney transplants to all multi-organ transplants involving a kidney has also increased during that time.[67] Simultaneous lung-kidney transplants are relatively rare, with just 11 of these transplants performed in

[56] B. A. Yerokun, M. S. Mulvihill, A. A. Osho, et al., "Simultaneous or Sequential Lung-Kidney Transplantation Confer Superior Survival in Renal-Failure Patients Undergoing Lung Transplantation: A National Analysis," *The Journal of Heart and Lung Transplantation* 36, no. 4 (April 2017): S95, https://doi.org/10.1016/j.healun.2017.01.240.
[57] Heidi J. Reich, Joshua L Chan, Lawrence S. C. Czer, et al., "Combined Lung-Kidney transplantation: An Analysis of the UNOS/OPTN Database," *The American Surgeon* 81, no. 10 (October 2015): 1047-1052, https://pubmed.ncbi.nlm.nih.gov/26463306/.
[58] Srinivas et al., "An Emerging Population," 1883.
[59] Cassuto et al., "Wait List Death," 2509.
[60] Lonze et al., "Kidney Transplantation," 583.
[61] Cassuto et al., "Wait List Death," 2510.
[62] Lonze et al., "Kidney Transplantation," 583.
[63] Asishana A. Osho, Sameer A. Hirji, Anthony W. Castleberry, et al., "Long-term survival following kidney transplantation in previous lung transplant recipients – An analysis of the UNOS registry," *Clinical Transplantation* 31 (2017): e12953, https://doi.org/10.1111/ctr.12953.
[64] Lonze, "Kidney Transplantation," 582.
[65] Osho, "Long-term survival," 8.
[66] OPTN data as of May 31, 2021.
[67] OPTN data as of May 31, 2021. Data shown do not reflect the total volume of transplants performed in the U.S. in this timeframe.

2020.[68] Regardless, establishing eligibility criteria for MOT candidates helps to achieve the best use of these scarce resources.[69] The OPTN previously established eligibility criteria and safety net policies for simultaneous liver-kidney allocation but has not yet implemented similar policies for other multi-organ combinations.

The Committee proposes implementing such policies for heart-kidney and lung-kidney allocation as a first step in a broader effort to develop more comprehensive multi-organ allocation policies that are based on eligibility criteria; that are ethical and equitable; and that improve the efficiency of organ allocation. Historically, allocation policy has required that kidneys be offered to candidates who are registered for a kidney and a heart or lung, regardless of a candidate's level of kidney dysfunction. To address this, the Committee proposes adding requirements to existing multi-organ policy that would ensure eligibility for both organs is limited to only those candidates who have a demonstrated clinical justification for both organs. The Committee proposes adding eligibility criteria related to kidney dysfunction to simultaneous heart-kidney and lung-kidney policy. Furthermore, the Committee proposes giving "safety net" priority to those candidates who received a heart or lung transplant, but need a kidney subsequent to those transplants. The prioritization acknowledges that such candidates' kidney function has not improved after the initial transplant.

Overview of Proposal

Similar to the eligibility criteria and safety net policies in place for simultaneous liver-kidney allocation, this proposal will establish eligibility criteria for simultaneous heart-kidney and simultaneous lung-kidney allocation, and safety net prioritization for heart or lung transplant recipients who subsequently demonstrate a need for a kidney transplant.

Eligibility Criteria

The Committee proposes that when an OPO is offering a heart or lung, and a kidney is also available from the same deceased donor, potential transplant recipients (PTRs) who meet the recommended eligibility criteria must be offered the kidney. If an OPO is offering a heart and a PTR is also registered for a kidney, then the OPO must offer the kidney if the PTR is registered at a transplant hospital at or within 500 nautical miles (NM) of the donor hospital, and if the PTR is assigned as an adult heart status 1, 2, or 3 and meets eligibility requirements, or the PTR is assigned any active pediatric heart status. If an OPO is offering a lung and a PTR is also registered for a kidney, then the OPO must offer the kidney if the PTR was less than 18 years old when registered on the lung waiting list, or has a Lung Composite Allocation Score of 28 or greater and meets eligibility requirements.

The 500 NM distance proposed for the heart-kidney eligibility criteria is consistent with current heart allocation policy and clarifications to multi-organ allocation policy that were approved by the OPTN Board of Directors in June 2021. Per OPTN *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 first classifications in heart allocation policy use a distance of 500 NM from the donor hospital.[70] The approved changes to clarify multi-organ allocation policy extended the distance for multi-organ allocation from 250 NM to 500 NM to better align with these heart allocation policies.[71]

[68] Ibid.
[69] "Ethical Implications of Multi-Organ Transplants," Briefing Paper, OPTN, accessed March 29, 2021, https://optn.transplant.hrsa.gov/media/2989/ethics_boardreport_201906.pdf.
[70] OPTN Policies, accessed January 21, 2022, https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.
[71] "Clarify Multi-Organ Allocation Policy," Briefing Paper, OPTN, accessed August 3, 2021, https://optn.transplant.hrsa.gov/media/4634/briefing-paper_june-2021_clarify-multi-organ-policy_draft.pdf.

Table 1 identifies the proposed medical eligibility criteria related to an adult heart or lung candidate's kidney function to qualify for a kidney offer along with the heart or lung.

Table 1: Proposed Eligibility Criteria for Certain Heart or Lung Candidates to Qualify for a Kidney From the Same Deceased Donor

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 measured or estimated glomerular filtration rate (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 measured or calculated creatinine clearance (CrCl) or GFR is less than or equal to 30 mL/min. • On a date after registration on the kidney waiting list, that the candidate's measured or calculated CrCl or GFR 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 measured or calculated CrCl or GFR 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 [heart or lung] and a kidney from the same donor.

Current OPTN policy precludes pediatric candidates from having to meet eligibility criteria for SLK. The Committee's consensus was that pediatric candidates should also be excluded from the medical eligibility criteria for simultaneous heart-kidney and lung-kidney transplantation.[72] Pediatric heart-kidney candidates, those registered on both waiting lists prior to turning 18 years old, would not be required to meet the proposed eligibility criteria. They would be eligible for simultaneous heart-kidney

[73] Meeting summary for August 16, 2021 meeting, OPTN Ad Hoc Multi-Organ Transplantation Committee, https://optn.transplant.hrsa.gov/media/meoabhv5/20210816_mot_meeting-summary_final.pdf (accessed November 8, 2021).

offers when registered on both the heart waiting list and the kidney waiting list. Additionally, lung-kidney candidates who are less than 18 years old when registered on the lung waiting list would not be required to meet the proposed medical eligibility criteria. They would be eligible when registered on both the lung and kidney waiting lists.

The Committee's consensus was that it is clinically appropriate to replicate SLK eligibility criteria for SHK and SLuK so that similar policies address patients with similar needs.[73] The majority of Committee members expressed support for this approach for several reasons.[74] First, it establishes consistency with the SLK policy that has been in place since 2017. The Committee members noted the lack of robust evidence supporting a need for different criteria for lung-kidney and heart-kidney candidates, since the eligibility criteria is based on the kidney function, and there is no clinical justification for measuring kidney function differently across the different organs. In making their decision, the MOT Committee members acknowledged that the low volume of lung-kidney transplants made it difficult to draw any comprehensive conclusions. With regard to heart-kidney transplantation, the Committee also cited the lack of comprehensive analysis as a challenge for recommending eligibility criteria different from what is established for SLK. The only deviation from the SLK eligibility criteria proposed by the Committee is to exclude the metabolic disease category from the eligibility criteria for SHK and SLuK. Lung Committee members provided feedback that they were not aware of any lung-kidney transplants due to metabolic disease and recommended removing the category as a result.[75] Similarly, Heart Committee members were not aware of any heart-kidney transplants performed due to metabolic disease.[76]

Safety Net

The Committee proposes safety net prioritization for kidney-after-heart and kidney-after-lung transplantation in line with current OPTN policy for the kidney-after-liver safety net. When the kidney-after-liver safety net was developed, the OPTN Kidney Transplantation Committee faced challenges related to limitations in the available data on kidney-after-liver transplantation. At the time, the Kidney Committee decided to take a conservative approach to the criteria for prioritizing safety net candidates.[77] Limiting eligibility to a core group of candidates was expected to produce very specific and accessible data on the advantages or disadvantages with the policy. By starting with limited eligibility, the Committee could also expand the eligibility if the need for changes was identified, as opposed to eliminating or restricting criteria that might disadvantage candidates. Because data analysis of heart-kidney and lung-kidney transplantation is also limited, the consensus of the MOT Committee members was to follow the precedent established for the kidney-after-liver safety net. The Committee holds that it is appropriate to start with a common threshold for safety net priority across multi-organ policies that could be adjusted in the future once the OPTN has collected more data. Accordingly, the Committee proposes expanding safety net prioritization in kidney allocation by adding heart recipients and lung recipients with post-operative dialysis dependency and significant kidney dysfunction in the first year following heart or lung transplant. Qualifying prior lung and heart recipients would receive the same

[73] Meeting summary for August 16, 2021 meeting, OPTN Ad Hoc Multi-Organ Transplantation Committee, https://optn.transplant.hrsa.gov/media/meoabhv5/20210816_mot_meeting-summary_final.pdf (accessed November 8, 2021).
[74] Meeting summary for August 16, 2021 meeting, OPTN Ad Hoc Multi-Organ Transplantation Committee, https://optn.transplant.hrsa.gov/media/meoabhv5/20210816_mot_meeting-summary_final.pdf (accessed November 8, 2021).
[75] Meeting presentation, for August 30, 2021 meeting, OPTN Ad Hoc Multi-Organ Transplantation Committee, https://bodandcommittees.unos.org/MOT/OPTNMaterials/Meeting%20Materials/2021_August_30_MOT_Draft.pptx?Web=1, (accessed December 1, 2021).
[76] Meeting summary for September 21, 2021 meeting, OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/ju1jptbx/20210921_heart-committee-meeting-summary_final.pdf (accessed December 22, 2021).
[77] Meeting summary for May 24, 2021 meeting, OPTN Ad Hoc Multi-Organ Transplantation Committee, https://optn.transplant.hrsa.gov/media/4688/20210524_mot_meeting-summary_final.pdf (accessed December 6, 2021).

priority in kidney allocation as prior liver recipients through the "Inside Circle Safety Net" classification shown below in **Table 2**.[78] "Inside Circle" refers to a 250 NM circle around the donor hospital.

The proposed policy states that a candidate registered on the kidney waiting list, who has received a heart or lung transplant, but not a heart and kidney or lung and kidney from the same deceased donor, would be classified as a prior heart recipient or prior lung recipient. A kidney candidate who is also identified as a prior heart or lung recipient is prioritized on the kidney waiting list if both of the following criteria are met:

- The candidate is registered on the kidney waiting list prior to the one year anniversary of their most recent heart or lung transplant
- On a date that is at least 60 days but not more than 365 days after the candidate's heart or lung transplant date, at least one of the following criteria is met:
    - The candidate has a measured or estimated creatinine clearance or glomerular filtration rate less than or equal to 20 mL/min
    - The candidate is on dialysis

A kidney candidate meeting the safety net criteria remains at the classification for 30 days from the date of the qualifying test or treatment. If the transplant program reports additional qualifying tests or treatments, then the candidate will remain at the classification for 30 days from the most recent date of the test, or treatment. A candidate meeting the criteria for 90 consecutive days, as reported by the transplant program, will remain at the classification until being removed from the waiting list and the program will no longer need to provide updated data. The proposed policy also provides protections for the candidate in situations where the candidate met the appropriate criteria, but the transplant program was late in reporting the criteria or did not register the candidate within the 365-day timeframe.

Based on feedback from the OPTN Lung Transplantation Committee,[79] the MOT Committee considered extending the safety net window for lung recipients to 18 months, but ultimately decided there was not sufficient data to justify this deviation from the policy in place for liver recipients. This is an example of a policy change that could be made in the future if supported by OPTN data.

Currently, prior liver recipients eligible for the safety net receive some priority in kidney allocation for donor kidneys with a KDPI between 21% and 100%. This provision would also apply to heart recipients and lung recipients who are eligible for the safety net. **Table 2** identifies the limits associated with safety net match classification priority within each KDPI sequence. The Committee discussed further limiting the use of kidneys for safety net prioritization to only those kidneys with a KDPI of 35% or higher. The members acknowledged that this additional limitation would likely improve access to higher quality kidneys for kidney-alone candidates.[80] However, the Committee ultimately decided that maintaining consistency, at least initially, with the kidney-after-liver safety net was appropriate. First, there is limited heart-kidney and lung-kidney transplantation data supporting such a change. Second, consistency with existing policy enables collection of comparative data that could be used to make future policy changes.[81] Finally, there will be additional opportunities to reconsider safety net priority in kidney

[78] Meeting summary for June 21, 2021 meeting, Ad Hoc Multi-Organ Transplantation Committee, https://optn.transplant.hrsa.gov/media/4713/20210621_mot_meeting-summary_final.pdf, (accessed December 22, 2021).
[79] Meeting summary for August 26, 2021, meeting, OPTN Lung Transplantation Committee, https://optn.transplant.hrsa.gov/media/ztvkdf4n/20210826_lung-committee-meeting-summary.pdf, (accessed December 22, 2021).
[80] Meeting summary for July 26, 2021 meeting, Ad Hoc Multi-Organ Transplantation Committee, https://optn.transplant.hrsa.gov/media/t2bnyvgk/20210726_mot_meeting-summary.pdf (accessed December 6, 2021).
[81] Meeting summary for July 26, 2021 meeting, Ad Hoc Multi-Organ Transplantation Committee, https://optn.transplant.hrsa.gov/media/t2bnyvgk/20210726_mot_meeting-summary.pdf (accessed December 6, 2021).

allocation as kidneys shift to a continuous distribution allocation framework. The OPTN Kidney Committee is requesting feedback this public comment cycle on defining a rating scale for a kidney-after-liver safety net attribute in the kidney composite allocation score as part of their Request for Feedback entitled *Update on Continuous Distribution of Kidneys and Pancreata*.[82]

Table 2: Current Safety Net Priority in Kidney Allocation

Sequence A KDPI: 0% to ≤20% (and en bloc)	Sequence B KDPI: >20% to <35%	Sequence C KDPI: ≥35% to ≤85%	Sequence D KDPI: >85%
• 100% Highly Sensitized[a] • Inside Circle Prior Living Donor[a] • Inside Circle Pediatrics[a] • Inside Circle Medically Urgent[b] • 98%-99% Highly Sensitized • 0-ABDRmm • Inside Circle Top 20% • EPTS • 0-ABDRmm (All) • Inside Circle (All) • National Pediatrics • National (Top 20%) • National (All)	• 100% Highly Sensitized[a] • Inside Circle Prior Living Donor[a] • Inside Circle Pediatrics[a] • Inside Circle Medically Urgent[b] • 98%-99% Highly Sensitized • 0-ABDRmm • **Inside Circle Safety Net** • Inside Circle (All) • National (All)	• 100% Highly Sensitized[a] • Inside Circle Prior Living Donor[a] • Inside Circle Medically Urgent[b] • 98%-99% Highly Sensitized • 0-ABDRmm • **Inside Circle Safety Net** • Inside Circle (All) • National (All) • Inside Circle (Dual) • National (Dual)	• 100% Highly Sensitized[a] • Inside Circle Medically Urgent[b] • 98%-99% Highly Sensitized • 0-ABDRmm • **Inside Circle Safety Net** • Inside Circle (All) • Inside Circle (Dual) • National (All) • National (Dual)

[a] Medically urgent sorted above non-medically urgent
[b] Medically urgent classification
Note: KDPI-Kidney donor profile index; 0-ABDRmm-No mismatches for HLAA, B, and DR; EPTS-Estimated post-transplant survival; Inside Circle Safety Net refers to prior liver, heart, and lung recipients in the 250 NM distribution circle who qualify for safety net prioritization.
Source: "Addressing Medically Urgent Candidates in the New Kidney Allocation System," OPTN website, https://optn.transplant.hrsa.gov/learn/professional-education/kidney-allocation-system/addressing-medically-urgent-candidates-in-the-new-kidney-allocation-system/#TK_FAQ (accessed November 8, 2021).

The Committee also considered whether safety net prioritization should apply to heart and lung recipients who received their heart and lung transplants outside of the United States. Currently, safety net policy applies to liver recipients who received their liver transplant outside of the United States and who are also registered for a kidney in the U.S. The Committee noted that this practice is extremely rare in heart and lung recipients and proposes implementing the same approach for heart and lung recipients who received their transplants outside of the United States, and who are now registered on the kidney waiting list in the U.S. Adopting the same approach as for liver recipients permits data collection and analysis based on actual practice, which can be used in contemplating future policy revisions, if necessary.

Expected Impact

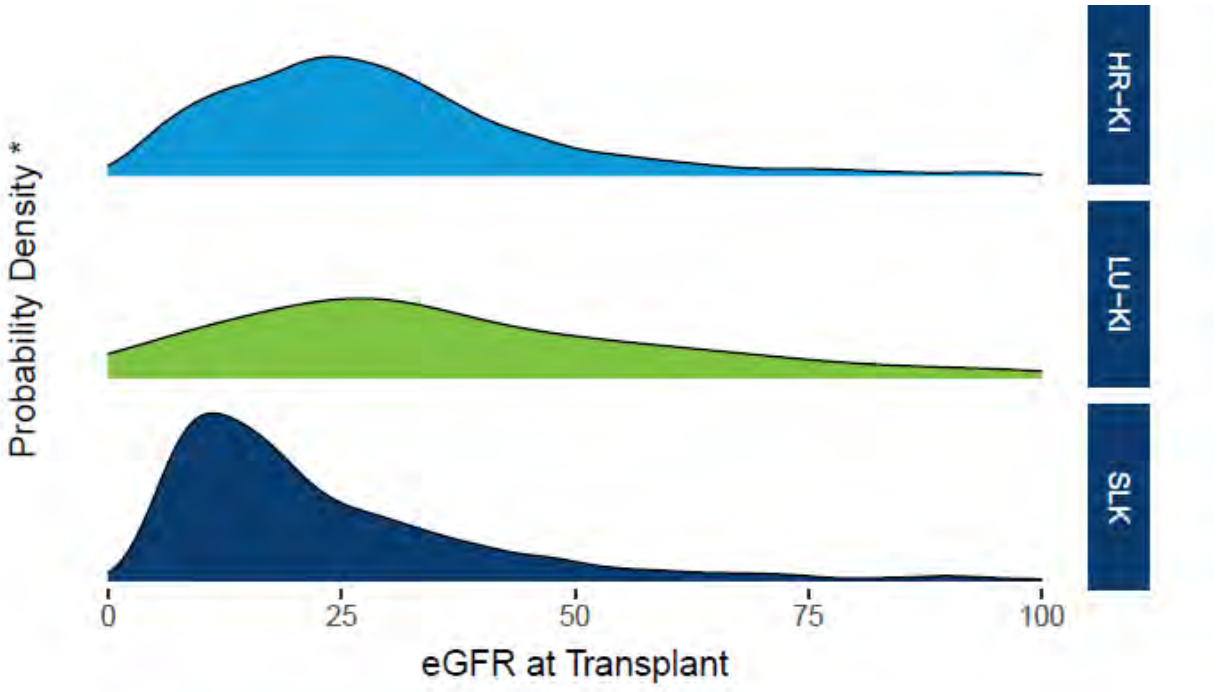
Prior to the implementation of SLK policy, there were concerns that the rising volume of SLK transplants was resulting in required shares of high quality kidneys along with livers, thereby pulling kidneys away

[82] "Public comment," OPTN, accessed January 24, 2022, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/.

from kidney-alone candidates, particularly pediatric candidates.[83] Similar concerns have been raised related to the rising frequency of other multi-organ transplants involving kidneys.[84]

Overall, the Committee expects that establishing medical eligibility criteria will slow the rising volume of simultaneous heart-kidney transplants, thereby increasing the number of kidneys offered to kidney-alone candidates and possibly improving access to transplantation for both adult and pediatric kidney-alone candidates. OPTN data show that in the absence of eligibility criteria, heart-kidney and lung-kidney recipients tend to be transplanted with higher levels of kidney function relative to liver-kidney recipients, as indicated by eGFR at transplant (**Figure 3**). Furthermore, a two-year review of SLK policy found that the percent of deceased donor kidney transplants that went to liver recipients decreased, and the actual number of SLK transplants was lower than a counterfactual forecast had the policy not been implemented.[85] There have not been any concerning declines in pediatric deceased donor kidney transplant volume since SLK policy was implemented in 2017, though other policies have been implemented in this time frame as well.[86]

Figure 3: Estimated Glomerular Filtration Rate at Transplant for Heart-Kidney, Lung-Kidney, and Liver-Kidney Recipients from August 10, 2017, to May 31, 2021



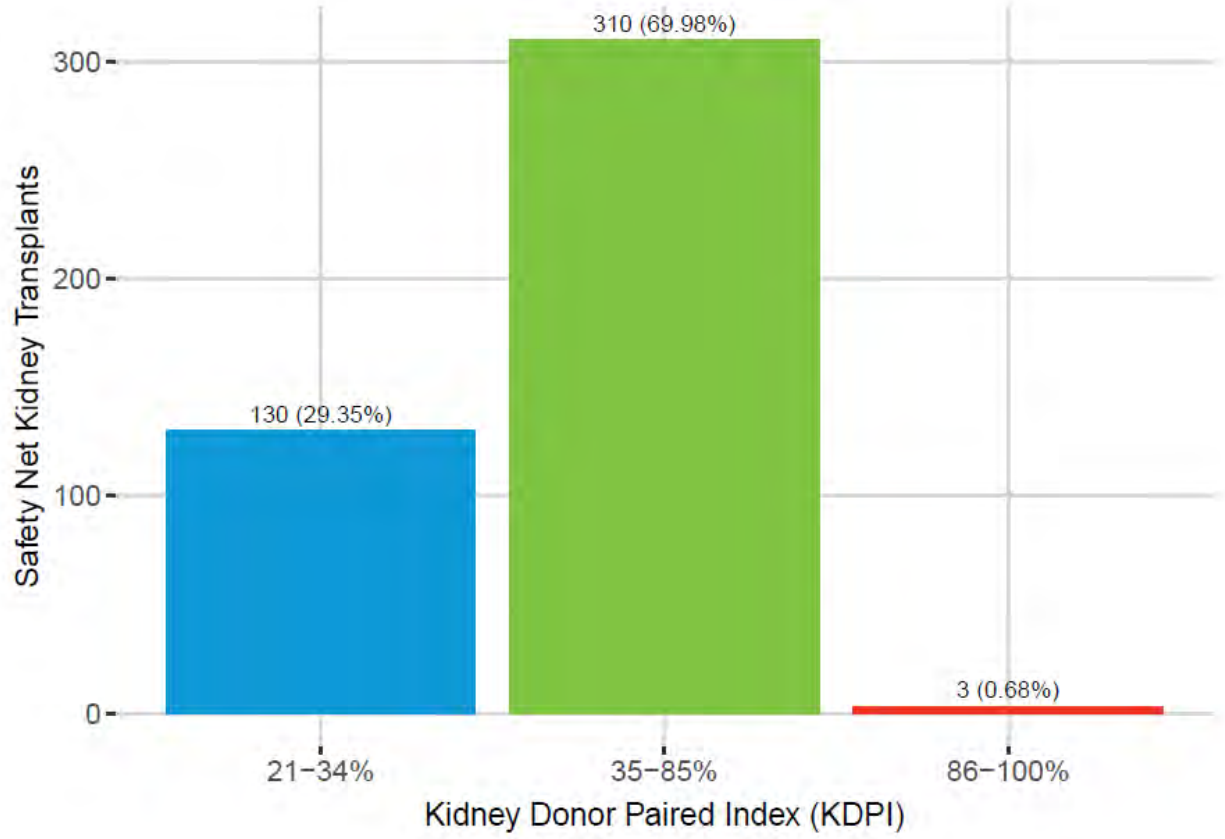
* High probability density values mean that a high percentage of the population lies at or around the corresponding x−axis value, and vice versa. 6 heart−kidney recipients, 1 lung−kidney recipient, and 50 liver−kidney recipients had an eGFR at transplant over 100.

With regard to the quality of kidneys allocated for multi-organ transplantation versus single-organ

[83] "Simultaneous Liver-Kidney Allocation," Briefing Paper, OPTN, accessed January 24, 2022, https://optn.transplant.hrsa.gov/media/1871/kidney_briefingpaper_slk_201606.pdf.
[84] Scott G. Westphal, Eric D. Langewisch, Amanda M. Robinson, et al., "The impact of multi-organ transplant allocation priority on waitlisted kidney transplant candidates" *American Journal of Transplantation* 00 (2020): 1-14, DOI: 10.1111/ajt.16390.
[85] Amber R. Wilk, Sarah E. Booker, Darren E. Stewart, et al., "Developing simultaneous liver-kidney transplant medical eligibility criteria while providing a safety net: A 2-year review of the OPTN's allocation policy," *American Journal of Transplantation* 21(2021): 3593-3607, DOI: 10.1111/ajt.16761.
[86] OPTN data as of December 31, 2021. Generally, pediatric deceased donor kidney transplant volume has remained stable. There were 728 pediatric kidney transplants in 2016; 746 in 2017; 755 in 2018; 760 in 2019; 710 in 2020; and 819 in 2021.

transplantation, this proposal would not specify any requirements for the quality of organs allocated to simultaneous multi-organ candidates but it would place some limits on the quality of organs offered to safety net candidates. Data from implementation of the kidney-after-liver safety net indicates that most prior liver recipients who receive a kidney through the safety net classification receive a kidney with a KDPI between 35-85% (**Figure 4**). The safety net does not give priority for the highest quality kidneys (those with a KDPI from 0-20%), but pediatric kidney-alone candidates are prioritized to receive offers for those kidneys. For safety net patients who do receive a kidney, the median days between kidney registration and transplant is 109 days.[87]

Figure 4. Quality of Kidneys Allocated Through the Kidney-After-Liver Safety Net from August 10, 2017, to May 31, 2021



Strategic Plan

Establishing policies for eligibility criteria and safety net prioritization for multi-organ combinations involving kidneys aligns with the OPTN strategic plan goal to provide equity in access in transplants, under which "improv[ing] equity in transplant opportunities for multi-organ and single-organ candidates" is a key initiative.[88]

[87] Wilk et al., "Developing simultaneous liver-kidney transplant medical eligibility criteria," 3600.
[88] "Strategic Plan 2021-2024," OPTN, accessed June 24, 2021, https://optn.transplant.hrsa.gov/media/4632/optn-strategic-plan-2021-2024.pdf.

Data Collection

The MOT Committee sought input and guidance from the OPTN Data Advisory Committee (DAC) during the development of this proposal to improve data quality and to ensure that proposed changes to OPTN data collection are aligned with the OPTN Principles for Data Collection.[89] The DAC evaluated the potential data burden of the proposal and endorsed the project.[90]

New data elements would be added to the Heart, Lung, and Heart-Lung candidate registration records as part of the simultaneous heart-kidney and lung-kidney eligibility criteria. The data elements would consist of the candidate's diagnosis of either chronic kidney disease (CKD) or sustained acute kidney injury (AKI); the date of the diagnosis of CKD or the date of test or treatment for sustained AKI; confirmation of dialysis or the candidate's CrCl or GFR measurements; and the name of the nephrologist who confirmed the candidate's diagnosis. These data elements are already collected as part of the Liver candidate record.

Upon implementation of the proposed safety net policies, all heart and lung recipients who meet the criteria within 60 to 365 days after their transplants would be eligible for safety net priority in kidney allocation. Implementation of the safety net criteria would require programming to identify whether a candidate has received a prior heart, lung, or heart-lung transplant, and then to confirm if the candidate meets other qualifying criteria. The OPTN computer match system, UNet^{SM}, is already programmed to determine if kidney candidates received a previous liver transplant and meet safety net criteria. New programming would enable the system to determine if a kidney candidate previously received a heart, lung, or heart-lung transplant.

Transplant programs would need to submit additional data to the OPTN to demonstrate whether their candidates meet the eligibility criteria for simultaneous transplant or priority for a kidney transplant under the safety net policy. This proposed data collection aligns with the OPTN Data Collection Principles to fulfill the requirements of the OPTN Final Rule; develop transplant, donation, and allocation policies; and determine if institutional members are complying with policy.[91]

NOTA and Final Rule Analysis

The Committee submits this proposal for consideration under the authority of NOTA, which 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,"[92] which "shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate."[93] This proposal impacts allocation as it would create rules to establish when a transplant candidate is eligible to receive a kidney along with a heart or lungs from the same donor, and would create a safety net to give priority to kidney candidates who previously received a heart or lung transplant.

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

[89] "Principles for Data Collection," OPTN, accessed April 2, 2021, https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/.
[90] OPTN Data Advisory Committee, OPTN, Meeting Summary, April 12, 2021, accessed May 25, 2021, https://optn.transplant.hrsa.gov/media/4585/20210412_dac_meeting_summary.pdf.
[91] "Principles for Data Collection," OPTN, accessed April 2, 2021, https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/.
[92] 42 U.S.C. §274(b)(2)(B).
[93] 42 CFR §121.8(a)(4).

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." This proposal:

- **Is based on sound medical judgment:**[94] 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 peer-reviewed literature, including analyses of changes in liver-kidney policy that demonstrate the desired changes sought with heart-kidney and lung-kidney policy revisions.[95,96]
- **Seeks to achieve the best use of donated organs:**[97] This proposal establishes eligibility criteria for simultaneous heart-kidney and simultaneous lung-kidney transplantation based on a candidate's kidney function for when an OPO must offer both the heart and kidney and the lungs and kidney for simultaneous transplant. Evidence suggests that simultaneous heart-kidney transplantation results in a survival advantage to the recipients compared to recipients of heart-alone transplants who have kidney impairment.[98,99] While the number of simultaneous lung-kidney transplants is small by comparison, some research studies have reported similar survival benefits.[100,101]
- **Is designed to avoid futile transplants**[102]**:** This proposal should not result in transplanting patients who are unlikely to have good post-transplant outcomes. Evidence suggests that recipients of simultaneous heart-kidney and lung-kidney transplants have better post-transplant outcomes than heart-alone or lung-alone recipients who need dialysis following transplant.[103,104] Studies also show that heart and lung recipients who receive a kidney transplant survive longer than heart and lung recipients who remain on the kidney waiting list.[105,106]
- **Is designed to…promote patient access to transplantation**[107]**:** This proposal gives similarly situated candidates equitable opportunities to receive an organ offer. Currently, eligibility for heart-kidney and lung-kidney transplantation is based on a candidate's proximity to the donor hospital and his or her medical urgency for the heart or lung. The candidate's kidney dysfunction is not considered. Adding kidney dysfunction as a qualifying criteria for simultaneous heart-kidney transplant eligibility helps ensure that similarly situated candidates have equitable opportunities to receive both organs. It also helps ensure that candidates who undergo single-organ transplant are not disadvantaged if a second organ subsequently fails. The same is true for candidates who need lung-kidney transplants. Additionally, the safety net prioritization

[94] 42 CFR §121.8(a)(1)
[95] Amber R. Wilk, et al., "Developing Simultaneous Liver-Kidney Transplant Medical Eligibility Criteria While Providing a Safety Net: A 2-year Review of the OPTN's Allocation Policy," *Am J Transplant*, 2021;21:3593-3607.
[96] OPTN Descriptive Data Request. "OPTN Simultaneous Liver Kidney (SLK) Allocation Policy Two Year Monitoring Report." Prepared for OPTN Kidney Transplantation Committee Meeting, May 18, 2020.
[97] 42 CFR §121.8(a)(2)
[98] Karamlou et al., "Combined heart-kidney transplant improves post-transplant survival," 456-461.
[99] Kilic et al., "The Survival Benefit of Simultaneous Heart-Kidney Transplantation," 1321-1327.
[100] Yerokun et al., "Simultaneous or Sequential Lung-Kidney Transplantation," S95.
[101] Reich et al., "Combined Lung-Kidney transplantation," 1047-1052.
[102] 42 CFR §121.8(a)(5).
[103] Kilic et al., "The Survival Benefit of Simultaneous Heart-Kidney Transplantation," 1324.
[104] Yerokun et al., "Simultaneous or Sequential Lung-Kidney Transplantation," 228.
[105] Lonze et al., "Kidney Transplantation, 582.
[106] Osho et al., "Long-term survival," 8.
[107] 42 CFR §121.8(a)(5).

requirements ensure access to those candidates in need of a kidney following heart or lung transplant who may have benefitted from simultaneous transplant. This proposal is expected to maintain access to transplantation for pediatric heart-kidney and lung-kidney candidates and improve access to transplantation for pediatric kidney-alone candidates. Consistent with approved policy, OPOs would be required to offer the kidney to any pediatric heart candidate within 500 NM from the donor hospital who is registered for both a heart and a kidney. Similarly, the OPO would be required to offer the kidney to any candidate who was less than 18 years old when registered on the lung waiting list and is registered for both a lung and a kidney. Pediatric kidney-alone candidates are prioritized above safety net candidates in kidney allocation and are expected to have more access to kidneys that otherwise might have been allocated to simultaneous heart-kidney or lung-kidney candidates.

- **Is designed to…promote the efficient management of organ placement:**[108] This proposal provides clear rules for when a kidney must be offered with the heart or lung. This may reduce the size of the pool of candidates to which an OPO must offer a kidney along with a heart or lung before offering the kidney to a kidney-alone candidate, potentially streamlining and improving the efficiency of allocating these organs.
- **Is not based on the candidate's place of residence or listing, except to the extent required to achieve the best use of organs.**[109] The best use of organs may provide justification for constraining geographic distribution of organs due to the impact on ischemic time, travel logistics, utilization and outcomes.[110] The proposed eligibility criteria governing simultaneous heart-kidney transplantation requires that a PTR registered at a transplant hospital within 500 NM of the donor hospital is offered both organs, among other requirements. The use of 500 NM aligns with the highest priority classification rows established in current heart policy.[111,112] This helps ensure the heart and kidney will be allocated to candidates with the highest medical urgency for both organs within the eligibility requirements governing kidney function. For lung, any consideration of geographic distribution is captured by the PTR's lung composite allocation score[113] and is not altered by this proposal.

This proposal also preserves the ability of a transplant program to decline and offer or not use the organ for a potential recipient,[114] and it is specific to various combinations of organ types.[115]

The Committee does not expect impacts on the aspect of the Final Rule associated with the avoidance of wasting organs (defined as organs recovered but not transplanted).[116]

The Final Rule also requires the OPTN to "consider whether to adopt transition procedures" whenever organ allocation policies are revised.[117] The Committee did not identify any populations who 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

[108] 42 CFR §121.8(a)(5).
[109] 42 CFR §121.8(a)(8).
[110] 42 CFR §121.8.
[111] OPTN Policy 6.6.D, *Allocation of Hearts from Donors at Least 18 years Old*, https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf (accessed December 7, 2021).
[112] OPTN Policy 6.6.E, *Allocation of Hearts from Donors Less Than 18 Years Old*, https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf (accessed December 7, 2021).
[113] "Establish Continuous Distribution of Lungs," Briefing Paper, OPTN, accessed January 24, 2022, https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf.
[114] 42 CFR §121.8(a)(3).
[115] 42 CFR §121.8(a)(4).
[116] 42 CFR §121.8(a)(5).
[117] 42 CFR §121.8(d).

transition procedures. Still, the Committee recognized that heart, lung, and kidney transplant programs would be required to report new information on the respective waiting lists, and document new information in their candidates' medical records, if the proposed changes are approved. To assist transplant programs in preparing for these changes, the new data fields would be made available in UNet in advance of the implementation date to allow programs to add the new data. A similar effort was employed with the implementation of SLK policy.[118] As part of the programming efforts at the time, the transplant community was notified that when the system changes were implemented, each candidate's record in UNet would need to demonstrate that he or she met the eligibility requirements at that time.

Additionally, the Committee submits this proposal under the authority of the OPTN Final Rule requiring the OPTN to "maintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors..."[119] and to "maintain records of all transplant candidates, all organ donors and all transplant recipients."[120] This proposal would affect information and records pertaining to transplant candidates by adding data collection associated with proposed eligibility criteria and safety net policies to indicate whether the transplant candidates meet the eligibility criteria or qualify for the safety net.

Implementation Considerations

Member and OPTN Operations

The OPTN, organ procurement organizations, and transplant hospitals that perform heart-kidney, lung-kidney, and kidney transplants would need to take action to implement this proposal, but this proposal is not anticipated to affect the operations of histocompatibility laboratories.

Operations affecting the OPTN

The OPTN is working sequentially to develop continuous distribution allocation systems for deceased donor organs.[121] A proposal to shift allocation of deceased donor lungs to continuous distribution[122] was approved by the OPTN Board of Directors in December 2021.[123] The OPTN Kidney and Pancreas Transplantation Committees are working on a proposal to transition the kidney and pancreas allocation systems to a continuous distribution framework,[124] and the OPTN Heart Committee is expected to start work on continuous distribution of deceased donor hearts in January 2023.[125]

If approved, the OPTN expects to implement the proposed eligibility criteria and safety net after continuous distribution of lungs but prior to continuous distribution of kidney and pancreas. Accordingly, the proposed eligibility criteria uses a lung composite allocation score threshold and does

[118] "Simultaneous liver kidney allocation education," OPTN, accessed January 24, 2022, https://optn.transplant.hrsa.gov/professionals/by-organ/liver-intestine/simultaneous-liver-kidney-allocation-education/.
[119] 42 CFR §121.11(a)(1)(i).
[120] 42 CFR §121.11(a)(1)(ii).
[121] "Continuous Distribution," OPTN, accessed January 24, 2022, https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/.
[122] "Establish Continuous Distribution of Lungs," OPTN, accessed January 24, 2022, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/establish-continuous-distribution-of-lungs/.
[123] "OPTN Executive Summary of the OPTN Board of Directors Meeting," OPTN, December 6, 2021, https://optn.transplant.hrsa.gov/media/g23hdtxk/20211206-optn-bod-summary.pdf.
[124] "Update on Continuous Distribution of Kidneys and Pancreata," Concept Paper, OPTN, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/update-on-continuous-distribution-of-kidneys-and-pancreata/ (accessed December 12, 2021), and "Update on Continuous Distribution of Kidneys and Pancreata," Request for Feedback, OPTN, January – March 2021, public comment period.
[125] "Continuous Distribution," OPTN.

not have an associated geographic boundary because the composite allocation score accounts for distance. A geographic distance is used for heart since heart will still be in a classification-based allocation system. The proposed eligibility criteria and most of the details of the safety net could be carried forward into continuous distribution of kidneys. The only aspect of this proposal that would need to be updated for continuous distribution of kidneys is the safety net priority in kidney allocation as shown in **Table 2**. The Kidney Committee has identified the safety net as an attribute that will be incorporated into the kidney composite allocation score, and the Kidney Committee will determine how much weight this attribute should have in the overall allocation score relative to other attributes.[126] As mentioned previously, the Kidney Committee is requesting feedback this public comment cycle on this attribute as part of their Request for Feedback entitled *Update on Continuous Distribution of Kidneys and Pancreata*.[127]

The OPTN will also need to update UNet to reflect the changes to allocation across multiple organ match runs, and update its evaluation plan for monitoring member performance. This proposal requires the submission of official OPTN data that are not presently collected by the OPTN. The OPTN Contractor has agreed that data collected pursuant to the OPTN's regulatory requirements in §121.11 of the OPTN Final Rule will be collected through OMB approved data collection forms. Therefore, after OPTN Board approval, the revised forms will be submitted for OMB approval under the Paperwork Reduction Act of 1995. This will require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline.

Operations affecting Organ Procurement Organizations

OPOs would need to train staff regarding new allocation policies for simultaneous heart-kidney and lung-kidney transplantation and kidney-after-heart and kidney-after-lung safety nets.

Operations affecting Transplant Hospitals

Transplant hospitals that perform heart-kidney, lung-kidney, and kidney transplants would need to train staff on new data collection for candidates needing heart-kidney, lung-kidney, kidney-after-heart, or kidney-after-lung transplants, as well as changes in access to multi-organ versus single-organ transplantation for these candidates.

Projected Fiscal Impact

This proposal is projected to have a fiscal impact on the OPTN, and a minimal fiscal impact on transplant hospitals and organ procurement organizations, and no impact on histocompatibility laboratories.

Projected Impact on the OPTN

The OPTN supported Committee meetings and leadership calls, along with policy drafting, review, revisions, and Committee voting.

The proposed policy changes would require updates to UNet. This includes programming updates in Waitlist℠ to address the heart-kidney and lung-kidney eligibility criteria and safety net prioritization for heart and lung recipients, as well as to add new data fields. The changes would require testing to ensure that allocation functions as described in policy.

[126] "Update on Continuous Distribution of Kidneys and Pancreata," OPTN.
[127] "Public comment," OPTN, accessed January 24, 2022, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/.

Projected Impact on Organ Procurement Organizations

This proposal should not have significant impact on current workflow, but it would require training and additional data collection and entry. It should not take more than one month for OPOs to train staff on the updates to allocation.

Projected Impact on Transplant Hospitals

This proposal should not have significant impact on current workflow, but it would require training and additional data collection and data entry. It should not take more than one month for transplant programs to train staff on the updates to allocation, which is estimated to add 10-15 minutes of additional data entry time per patient.

This proposal is not expected to have an impact on ongoing costs.

Projected Impact on Histocompatibility Laboratories

No impact.

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."[128] 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.

During site surveys of transplant hospitals, the OPTN will review a sample of medical records, and any material incorporated into the medical record by reference, to verify that the following data reported in UNet are consistent with source documentation available at the time of entry:

- For recipients receiving a heart-kidney or lung-kidney transplant based on a diagnosis of CKD:
    - Regularly administered dialysis for ESRD
    - Measured or estimated creatinine clearance (CrCl) or glomerular filtration rate (GFR) less than or equal to 30 mL/min on either:
        - The date of the most recent result before registration on the kidney waiting list
        - A date after registration on the kidney waiting list
- For recipients receiving a heart-kidney or lung-kidney transplant based on a diagnosis of sustained acute kidney injury:
    - Dates of dialysis received
    - Measured or estimated creatinine clearance or GFR values less than or equal to 25 mL/min and the corresponding collection dates for each value

The OPTN will also review a sample of medical records, and any material incorporated into the medical record by reference, of kidney recipients who received priority for a kidney due to a prior heart or lung transplant, to verify that data reported in UNet are consistent with source documentation, including the most recent dates and results for any of the following:

[128] 42 CFR §121.8(a)(7).

- Measured or estimated creatinine clearance
- Measured or estimated GFR
- Dialysis

Policy Evaluation

The Final Rule requires that allocation policies "be reviewed periodically and revised as appropriate."[129] Monitoring reports using pre vs. post comparisons would be presented to the Committee after approximately 6 months, 1 year and 2 years. Metrics include:

Waiting List:

- Volume of heart-kidney and lung-kidney registrations by eligibility criteria and subcriteria and heart status for heart-kidney registrations
- Waiting list mortality for heart-kidney and lung-kidney candidates who are eligible and not eligible for the kidney with the heart or lung
- Volume of kidney after heart and kidney after lung registrations (safety net) by eligibility criteria
- Waiting list mortality for heart and lung candidates that need a kidney following the thoracic transplant by safety net eligibility

Transplant:

- Volume of heart-kidney and lung-kidney transplants by eligibility criteria and subcriteria and heart status for heart-kidney transplants or lung composite allocation score for lung-kidney transplants
- Volume of kidney after heart and kidney after lung transplants (safety net) by eligibility criteria
- Percent of deceased donor kidneys being transplanted in heart and lung recipients.
- Percent of recipients with delayed Kidney graft function for multi-organ transplants and safety net
- Kidney graft survival for kidney alone, heart-kidney and lung-kidney recipients
- Heart graft survival for heart alone and heart-kidney recipients
- Lung graft survival for lung alone and lung-kidney recipients

Metrics would only be reported after a sufficient sample size has accumulated. The OPTN and SRTR contractors will work with the committee on any additional data requests related to the policy change.

Conclusion

This proposal would establish eligibility criteria for simultaneous heart-kidney and lung-kidney allocation. In addition, the proposal would establish a "safety net" for prior heart or lung transplant recipients who, subsequent to the transplant, have demonstrated a need for a kidney transplant by prioritizing such candidates in kidney allocation. This proposal would include new data collection on heart-kidney and lung-kidney transplant candidates as well as kidney candidates who are prior heart or lung recipients to enable the OPTN to determine whether candidates meet the eligibility criteria or safety net qualifications.

The MOT Committee seeks feedback on the following questions:

- Is it appropriate to use eligibility criteria for heart-kidney and lung-kidney allocation similar to the criteria used for simultaneous liver-kidney allocation?

[129] 42 CFR §121.8(a)(6).

- For heart-kidney candidates diagnosed with chronic kidney disease, is less than or equal to 30 mL/min the appropriate eGFR threshold to be eligible for simultaneous heart-kidney transplantation?
- Should adult status 4 heart candidates who are on dialysis be included with adult heart status 1, 2, and 3 candidates as part of the simultaneous heart-kidney eligibility criteria?
- Is the use of 500NM from the donor hospital an appropriate eligibility criterion for simultaneous heart-kidney allocation? Why or why not?
- Should the metabolic disease diagnosis in the eligibility criteria for simultaneous liver-kidney allocation also be included in the eligibility criteria for simultaneous heart-kidney and/or lung-kidney allocation?

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.

[GFR DEFINITION PROPOSED IN KIDNEY-MAC EGFR PROPOSAL]

1.2 Definitions

Glomerular Filtration Rate (GFR)
A measure of filtering capacity of the kidneys. GFR can be measure directly or estimated (eGFR) using various formulae. Formulae used to calculate an eGFR must not use a race based variable.

[ELIGIBILITY CRITERIA FOR HEART-KIDNEY AND LUNG-KIDNEY]

5.10 Allocation of Multi-Organ Combinations

5.10.A Allocation of Heart-Lungs

Heart-lung combinations are allocated according to *Policy 6.6.F: Allocation of Heart-Lungs*.

5.10.B Allocation of Liver-Kidneys

Liver-kidney combinations are allocated according to *Policy 9.9: Liver-Kidney Allocation*.

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 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 meets all of the following criteria:~~
~~Heart~~	~~Liver or Kidney~~	~~• Registered at a transplant hospital at or within 500 NM of the donor hospital~~ ~~• Heart Adult Status 1, 2, 3 or any active pediatric status~~
~~Lung~~	~~Liver or Kidney~~	~~Has a Lung Composite Allocation Score of 28 or greater~~

~~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.~~

5.10.E: Allocation of Heart-Kidneys

When an OPO is offering a heart, and a kidney is also available from the same deceased donor, then the OPO must offer the kidney to a potential transplant recipient (PTR) who is registered for a heart and a kidney at the same transplant hospital, and who meets either of the following criteria:

- PTR is registered at a transplant hospital at or within 500 NM of the donor hospital and is any active pediatric status, or
- PTR is registered at a transplant hospital at or within 500 NM of the donor hospital and heart adult status 1, 2, or 3, and meets the eligibility criteria established in *Table 5-4: Medical Eligibility Criteria for Heart-Kidney Allocation*

If a host OPO is offering a kidney and a heart from the same deceased donor, then before allocating the kidney to kidney-alone candidates, the host OPO must offer the kidney with the heart to candidates who meet either of the eligibility criteria described in Policy 5.10.E.

5.10.E.i: Heart-Kidney Candidate Eligibility for Candidates Less Than 18 Years Old When Registered on the Heart Waiting List

Candidates who were less than 18 years old when registered on the heart waiting list are eligible to receive a heart 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 heart to all candidates who were less than 18 years old at the time of registration.

5.10.E.ii: Heart-Kidney Candidate Eligibility for Candidates 18 Years Old or Older When Registered on the Heart Waiting List

Candidates who were 18 years old or older when registered on the heart waiting list are eligible to receive both a heart 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 5-4: Medical Eligibility Criteria for Heart-Kidney Allocation.*

Table 5-4: Medical Eligibility Criteria for Heart-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 measured or estimated glomerular filtration rate (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 measured or estimated creatinine clearance (CrCl) or GFR is less than or equal to 30 mL/min. • On a date after registration on the kidney waiting list, that the candidate's measured or estimated CrCl or GFR 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 measured or estimated CrCl or GFR 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 heart and a kidney from the same donor.

5.10.F: Allocation of Lung-Kidneys

When an OPO is offering a lung, and a kidney is also available from the same deceased donor, then the OPO must offer the kidney to a potential transplant recipient (PTR) who is registered for a lung and a kidney at the same transplant hospital, and who meets either of the following criteria:

- PTR was less than 18 years old when registered on the lung waiting list, or
- PTR has a Lung Composite Allocation Score of 28 or greater, and meets eligibility according to *Table 5-5: Medical Eligibility Criteria for Lung-Kidney Allocation*

If a host OPO is offering a kidney and a lung from the same deceased donor, then before allocating the kidney to kidney-alone candidates, the host OPO must offer the kidney with the lung to candidates who meet either of the eligibility criteria described in Policy 5.10.F.

5.10.F.i: Lung-Kidney Candidate Eligibility for Candidates Less Than 18 Years Old When Registered on the Lung Waiting List

Candidates who were less than 18 years old when registered on the lung waiting list are eligible to receive a lung 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 lungs to all candidates who were less than 18 years old at the time of registration.

5.10.F.ii: Lung-Kidney Candidate Eligibility for Candidates 18 Years Old or Older When Registered on the Lung Waiting List

Candidates who were 18 years old or older when registered on the lung waiting list are eligible to receive both a lung 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 5-5: Medical Eligibility Criteria for Lung-Kidney Allocation*.

Table 5-5: Medical Eligibility Criteria for Lung-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 measured or estimated glomerular filtration rate (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 measured or estimated creatinine clearance (CrCl) or GFR is less than or equal to 30 mL/min. • On a date after registration on the kidney waiting list, that the candidate's measured or estimated CrCl or GFR 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 measured or estimated CrCl or GFR 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 lung and a kidney from the same donor.

5.10.G Allocation of Heart-Liver and Lung-Liver

When an OPO is offering a heart or lung, and a liver is also available from the same deceased donor, PTRs who meet the criteria in *Table 5-6: When Offering a Heart or Lung and Second Organ Is a Liver* must be offered the liver. When an OPO is offering a heart or lung and two PTRs meet the criteria in *Table 5-6*, the OPO has the discretion to offer the liver to either PTR.

Table 5-6: When Offering a Heart or Lung and Second Organ Is a Liver

If an OPO is offering a heart or lung, and a PTR is also registered for a liver:	The OPO must offer the liver if the PTR meets the following criteria:
Heart	• Registered at a transplant hospital at or within 500 NM of the donor hospital • Heart Adult Status 1, 2, 3 or any active pediatric status
Lung	Has a Lung Composite Allocation Score of 28 or greater

It is permissible for the OPO to offer the liver to other PTRs who do not meet the criteria in Policy 5.10.G.

[SAFETY NET PRIORITIZATION]

8.5 Kidney Allocation Classifications and Rankings

8.5.G Prioritization for Liver Recipients on the Kidney Waiting List [*Policy 8.5.G* is provided as reference for comparing with *Policy 8.5.I* and *Policy 8.5.J*]

If a kidney candidate received a liver transplant, but not a liver and kidney transplant from the same deceased donor, the candidate will be classified as a prior liver recipient. This classification gives priority to a kidney candidate if *both* of the following criteria are met:

1. The candidate is registered on the kidney waiting list prior to the one-year anniversary of the candidate's most recent liver transplant date
2. On a date that is at least 60 days but not more than 365 days after the candidate's liver transplant date, at least *one* of the following criteria is met:
   - The candidate has a measured or ~~calculated~~ estimated creatinine clearance (CrCl) or glomerular filtration rate (GFR) less than or equal to 20 mL/min.
   - The candidate is on dialysis.

When the transplant program reports that the candidate meets the criteria for this classification, the candidate will remain at this classification for 30 days from the date of the qualifying test or treatment. If the transplant program reports additional qualifying tests or treatments, then the candidate will remain at this classification for 30 days from the most recent date of the test or treatment. If the transplant program reports that the candidate meets the criteria for 90 consecutive days, the candidate will remain at this classification until the candidate is removed from the kidney waiting list. If the candidate transfers kidney waiting time according to *Policy 3.6.C: Individual Waiting Time Transfers* and has met the criteria for 90 consecutive days, then the candidate's classification will be included in the transfer.

If a liver recipient receives a kidney using this priority classification and returns to the kidney waiting list after the most recent kidney transplant, the candidate must again meet the criteria for this classification, unless the candidate qualifies for kidney waiting time reinstatement according to *Policy 3.6.B.i: Non-function of a Transplanted Kidney.* If the candidate qualifies for kidney waiting time reinstatement, the candidate will be classified as qualifying for the classification.

If a kidney candidate received a liver and kidney transplant from the same deceased donor, the candidate will only qualify for this classification if the candidate qualifies for kidney waiting time reinstatement according to *Policy 3.6.B.i: Non-function of a Transplanted Kidney.*

8.5.H Prioritization for Heart Recipients on the Kidney Waiting List

If a kidney candidate received a heart transplant, but not a heart and kidney transplant from the same deceased donor, the candidate will be classified as a prior heart recipient. This classification gives priority to a kidney candidate if *both* of the following criteria are met:

1. The candidate is registered on the kidney waiting list prior to the one-year anniversary of the candidate's most recent heart transplant date
2. On a date that is at least 60 days but not more than 365 days after the candidate's heart transplant date, at least *one* of the following criteria is met:
    - The candidate has a measured or estimated creatinine clearance (CrCl) or glomerular filtration rate (GFR) less than or equal to 20 mL/min.
    - The candidate is on dialysis.

When the transplant program reports that the candidate meets the criteria for this classification, the candidate will remain at this classification for 30 days from the date of the qualifying test or treatment. If the transplant program reports additional qualifying tests or treatments, then the candidate will remain at this classification for 30 days from the most recent date of the test or treatment. If the transplant program reports that the candidate meets the criteria for 90 consecutive days, the candidate will remain at this classification until the candidate is removed from the kidney waiting list. If the candidate transfers kidney waiting time according to *Policy 3.6.C: Individual Waiting Time Transfers* and has met the criteria for 90 consecutive days, then the candidate's classification will be included in the transfer.

If a heart recipient receives a kidney using this priority classification and returns to the kidney waiting list after the most recent kidney transplant, the candidate must again meet the criteria for this classification, unless the candidate qualifies for kidney waiting time reinstatement according to *Policy 3.6.B.i: Non-function of a Transplanted Kidney.* If the candidate qualifies for kidney waiting time reinstatement, the candidate will be classified as qualifying for the classification.

If a kidney candidate received a heart and kidney transplant from the same deceased donor, the candidate will only qualify for this classification if the candidate qualifies for kidney waiting time reinstatement according to *Policy 3.6.B.i: Non-function of a Transplanted Kidney.*

8.5.I Prioritization for Lung Recipients on the Kidney Waiting List

If a kidney candidate received a lung transplant, but not a lung and kidney transplant from the same deceased donor, the candidate will be classified as a prior lung recipient. This classification gives priority to a kidney candidate if *both* of the following criteria are met:

1. The candidate is registered on the kidney waiting list prior to the one-year anniversary of the candidate's most recent lung transplant date
2. On a date that is at least 60 days but not more than 365 days after the candidate's lung transplant date, at least *one* of the following criteria is met:
    - The candidate has a measured or estimated creatinine clearance (CrCl) or glomerular filtration rate (GFR) less than or equal to 20 mL/min.
    - The candidate is on dialysis.

When the transplant program reports that the candidate meets the criteria for this classification, the candidate will remain at this classification for 30 days from the date of the qualifying test or treatment. If the transplant program reports additional qualifying tests or treatments, then the candidate will remain at this classification for 30 days from the most recent date of the test or treatment. If the transplant program reports that the candidate meets

the criteria for 90 consecutive days, the candidate will remain at this classification until the candidate is removed from the kidney waiting list. If the candidate transfers kidney waiting time according to *Policy 3.6.C: Individual Waiting Time Transfers* and has met the criteria for 90 consecutive days, then the candidate's classification will be included in the transfer.

If a lung recipient receives a kidney using this priority classification and returns to the kidney waiting list after the most recent kidney transplant, the candidate must again meet the criteria for this classification, unless the candidate qualifies for kidney waiting time reinstatement according to *Policy 3.6.B.i: Non-function of a Transplanted Kidney.* If the candidate qualifies for kidney waiting time reinstatement, the candidate will be classified as qualifying for the classification.

If a kidney candidate received a lung and kidney transplant from the same deceased donor, the candidate will only qualify for this classification if the candidate qualifies for kidney waiting time reinstatement according to *Policy 3.6.B.i: Non-function of a Transplanted Kidney.*

8.5.~~H~~J Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%

8.5.~~I~~K Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than 35%

Kidneys from deceased donors with KDPI scores greater than 20% but less than 35% are allocated to candidates according to *Table 8-8* below. For the purposes of *Table 8-8*, distribution will be based on the distance from the candidate's transplant hospital to the donor hospital, unless the kidney is allocated according to *Policy 8.8: Allocation of Released Kidneys*. For kidneys that are released and the host OPO or the OPTN executes a released kidney match run, distribution will be based on the distance from the candidate's transplant hospital to the transplant hospital that released the organ.

Table 8-8: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than 35%

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	250NM	Any
2	CPRA equal to 100%, blood type permissible or identical	250NM	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
3	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Nation	Any
4	CPRA equal to 100%, blood type permissible or identical	Nation	Any
5	Prior living donor, blood type permissible or identical	250NM	Any
6	Registered prior to 18 years old, blood type permissible or identical	250NM	Any
7	Medically Urgent	250NM	Any
8	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	250NM	Any
9	CPRA equal to 99%, blood type permissible or identical	250NM	Any
10	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	250NM	Any
11	CPRA equal to 98%, blood type permissible or identical	250NM	Any
12	0-ABDR mismatch, blood type identical	250NM	Any
13	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
14	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Nation	Any
15	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Nation	Any
16	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
17	0-ABDR mismatch, blood type B	250NM	O
18	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	O
19	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	Nation	O
20	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	Nation	O
21	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
22	0-ABDR mismatch, blood type permissible	250NM	Any
23	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
24	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type permissible	Nation	Any
25	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type permissible	Nation	Any
26	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
27	Prior liver, heart, and lung recipients ~~that~~who meet the qualifying criteria according to *Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List, Policy 8.5.H: Prioritization for Heart Recipients on the Kidney Waiting List*, or *Policy 8.5.I: Prioritization for Lung Recipients on the Kidney Waiting List,* blood type permissible or identical	250NM	Any
28	Blood type B	250NM	A2 or A2B
29	All remaining candidates, blood type permissible or identical	250NM	Any
30	Registered prior to 18 years old, blood type permissible or identical	Nation	Any
31	Blood type B	Nation	A2 or A2B
32	All remaining candidates, blood type permissible or identical	Nation	Any

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8.5.~~J~~L Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than or Equal to 35% but Less than or Equal to 85%

Kidneys from donors with KDPI scores greater than or equal to 35% but less than or equal to 85% are allocated to candidates according to *Table 8-9* below and the following:

- Classifications 1 through 30 for one deceased donor kidney
- Classification 31 and 32 for both kidneys from a single deceased donor

For the purposes of *Table 8-9*, distribution will be based on the distance from the candidate's transplant hospital to the donor hospital, unless the kidney is allocated according to *Policy 8.8: Allocation of Released Kidneys*. For kidneys that are released and the host OPO or the OPTN executes a released kidney match run, distribution will be based on the distance from the candidate's transplant hospital to the transplant hospital that released the organ.

Table 8-9: Allocation of Kidneys from Deceased Donors with KDPI Greater Than or Equal To 35% and Less Than or Equal To 85%

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	250NM	Any
2	CPRA equal to 100%, blood type permissible or identical	250NM	Any
3	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Nation	Any
4	CPRA equal to 100%, blood type permissible or identical	Nation	Any
5	Prior living donor, blood type permissible or identical	250NM	Any
6	Medically Urgent	250NM	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
7	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	250NM	Any
8	CPRA equal to 99%, blood type permissible or identical	250NM	Any
9	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	250NM	Any
10	CPRA equal to 98%, blood type permissible or identical	250NM	Any
11	0-ABDR mismatch, blood type identical	250NM	Any
12	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
13	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Nation	Any
14	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Nation	Any
15	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
16	0-ABDR mismatch, and blood type B	250NM	O

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
17	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	O
18	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	Nation	O
19	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	Nation	O
20	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
21	0-ABDR mismatch, blood type permissible	250NM	Any
22	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Nation	Any
23	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 years old at time of match, and blood type permissible	Nation	Any
24	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 years old at time of match, and blood type permissible	Nation	Any
25	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
26	Prior liver, heart, and lung recipients ~~that~~who meet the qualifying criteria according to *Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List, Policy 8.5.H: Prioritization for Heart Recipients on the Kidney Waiting List*, or *Policy 8.5.I: Prioritization for Lung Recipients on the Kidney Waiting List,* blood type permissible or identical	250NM	Any
27	Blood type B	250NM	A2 or A2B
28	All remaining candidates, blood type permissible or identical	250NM	Any
29	Blood type B	Nation	A2 or A2B
30	All remaining candidates, blood type permissible or identical	Nation	Any
31	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	250NM	Any
32	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	Nation	Any

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8.5.~~K~~M Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%

With the exception of 0-ABDR mismatches, kidneys from deceased donors with KDPI scores greater than 85% are allocated to adult candidates according to *Table 8-10* below and the following:

- Classifications 1 through 21, 23, and 24 for one deceased donor kidney
- Classifications 22 and 25 for both kidneys from a single deceased donor

For the purposes of Table 8-10, distribution will be based on the distance from the candidate's transplant hospital to the donor hospital, unless the kidney is allocated according to *Policy 8.8: Allocation of Released Kidneys*. For kidneys that are released and the host OPO or the OPTN executes a released kidney match run, distribution will be based on the distance from the candidate's transplant hospital to the transplant hospital that released the organ.

Table 8-10: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 85%

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
1	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	250NM	Any
2	CPRA equal to 100%, blood type permissible or identical	250NM	Any
3	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Nation	Any
4	CPRA equal to 100%, blood type permissible or identical	Nation	Any
5	Medically Urgent	250NM	Any
6	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	250NM	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
7	CPRA equal to 99%, blood type permissible or identical	250NM	Any
8	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	250NM	Any
9	CPRA equal to 98%, blood type permissible or identical	250NM	Any
10	0-ABDR mismatch, blood type permissible or identical	250NM	Any
11	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Nation	Any
12	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Nation	Any
13	0-ABDR mismatch, blood type B	250NM	O
14	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	Nation	O
15	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	Nation	O
16	0-ABDR mismatch, blood type permissible	250NM	Any
17	0-ABDR mismatch, CPRA greater than or equal to 80% , and blood type permissible	Nation	Any

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the hospital that distribution will be based upon	With this donor blood type:
18	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Nation	Any
19	Prior liver, heart, and lung recipients ~~that~~who meet the qualifying criteria according to *Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List, Policy 8.5.H: Prioritization for Heart Recipients on the Kidney Waiting List*, or *Policy 8.5.I: Prioritization for Lung Recipients on the Kidney Waiting List,* blood type permissible or identical	250NM	Any
20	Blood type B	250NM	A2 or A2B
21	All remaining candidates, blood type permissible or identical	250NM	Any
22	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	250NM	Any
23	Blood type B	Nation	A2 or A2B
24	All remaining candidates, blood type permissible or identical	Nation	Any
25	Candidates who have specified they are willing to accept both kidneys from a single deceased donor, blood type permissible or identical	Nation	Any

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~~ Allocation of Heart-Kidneys*
- *Policy 5.10.F: Allocation of Lung-Kidneys*
- *Policy 9.9: Liver-Kidney Allocation*
- *Policy 11.4.A: Kidney-Pancreas Allocation Order*

9.9 Liver-Kidney Allocation [*Policy 9.9* is provided as reference for comparing with eligibility criteria in *Policy 5.10.E and Policy 5.10.F*]

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*.

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 measured or ~~calculated~~ estimated glomerular filtration rate (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 measured or ~~calculated~~ estimated creatinine clearance (CrCl) or GFR is less than or equal to 30 mL/min. • On a date after registration on the kidney waiting list, that the candidate's measured or ~~calculated~~ estimated CrCl or GFR 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 measured or ~~calculated~~ estimated CrCl or GFR 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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