OPTN

Briefing to the OPTN Board of Directors on

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 implemented in February 2022[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 does not include any requirements for the candidate's kidney function.

The Ad Hoc Multi-Organ Transplantation (MOT) Committee proposes establishing eligibility criteria for simultaneous heart-kidney and lung-kidney allocation that adds requirements based on kidney function. The goal is to restrict required offers of multiple organs to candidates who have clinical justification to receive the kidney along with the heart or lung, thereby promoting access to transplantation for kidney-alone candidates. Additionally, the Committee proposes establishing a "safety net," which gives some priority in kidney allocation to heart and lung recipients who meet medical criteria for a kidney transplant within one year of their heart or lung transplant. Taken together, the proposed eligibility criteria and safety net 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) or kidney-after-liver allocation.

[1] "Clarify Multi-Organ Allocation Policy," OPTN, Policy Notice, https://optn.transplant.hrsa.gov/media/4698/clarify_multi-organ_june_2021_policy_notice.pdf.

Background

OPTN policies have historically required organ procurement organizations (OPOs) to allocate multiple organs from the same donor to MOT candidates meeting certain criteria. In 2017, the OPTN implemented more detailed policy requirements specific to simultaneous liver-kidney (SLK) allocation.[2] 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 SLK to more medically urgent liver candidates.[3] 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 need a kidney transplant (OPTN *Policy 8.5G: Prioritization for Liver Recipients on the Kidney Waiting List*).

Eligibility criteria are qualifying conditions for an OPO to offer a candidate a second organ (e.g. 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,[4,5] whereas 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.

A safety net gives recipients of a single-organ transplant some priority in allocation for a second organ (e.g. a kidney) shortly after the initial transplant. The intent of a safety net policy is to protect access to transplant for patients who do not recover function in a second organ after a single-organ transplant (SOT). The safety net can also promote good stewardship of scarce donor organs in that transplant programs may be more willing to proceed with a single-organ transplant for a patient if they know that the patient will be able to get a second organ, if needed, on an expedited timeframe.

In this way, policies addressing eligibility criteria and safety net priority work hand-in-hand to balance access to transplantation for single-organ candidates and multi-organ 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 safety net policies only for liver-kidney allocation. These policies successfully slowed the rise of SLK transplants and provided kidneys to prior liver recipients when needed, while preserving post-transplant outcomes.[6]

Updates to general multi-organ policy were implemented in February 2022.[7] The primary objective of these changes was to provide OPOs with clearer directions for when they must offer multiple organs to one candidate.[8,9] In part, the policy clarified when a kidney must be offered to a candidate along with a

[2] "Simultaneous liver-kidney allocation 2016," OPTN, accessed November 7, 2021, https://optn.transplant.hrsa.gov/governance/public-comment/simultaneous-liver-kidney-allocation-2016/.
[3] Mark I. Aeder, "Simultaneous Liver-Kidney Transplantation: Policy Update and the Challenges Ahead," *Current Transplantation Reports* 5 (2018): 130-138, https://doi.org/10.1007/s40472-018-0190-0.
[4] 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.
[5] 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.
[6] 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.
[7] "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).
[8] 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.
[9] "Clarify Multi-Organ Allocation Policy," Briefing Paper, OPTN, accessed August 3, 2021, https://optn.transplant.hrsa.gov/media/4634/briefing-

heart or lung, based on the candidate's medical urgency for the heart or lung and the candidate's distance from the donor hospital. During the public comment period for this policy change,[10] members raised concerns about perceived inequities related to MOT allocation, which include:

- Lack of medical eligibility requirements for any kidney MOT allocation policy beyond what is in place for SLK allocation[11,12,13,14]
- Increase in volume of heart-kidney transplants[15,16,17] following the 2018 implementation of heart allocation policies that gave more priority to sicker candidates[18,19]
- Imbalance between kidney single-organ versus kidney multi-organ allocation (including SLK)[20]
- 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)[21,22]

The OPO Committee acknowledged these issues but noted that their proposal was the first step in a larger effort to improve multi-organ allocation policies. As the OPO Committee worked on their proposal, a separate, ad hoc committee was established to further policy development on multi-organ allocation.[23] The Ad Hoc Multi-Organ Transplantation (MOT) Committee was charged with developing allocation policies in alignment with the OPTN Final Rule and the planned transition of each organ allocation system to a continuous distribution (CD) framework.[24,25] 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**.

paper_june-2021_clarify-multi-organ-policy_draft.pdf.

[10] "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/.

[11] Ibid.

[12] 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.

[13] 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

[14] 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.

[15] Ibid.

[16] Kidney & Pancreas Transplantation Committee Continuous Distribution Workgroup Meeting Summary, January 15, 2021, OPTN.

[17] 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.

[18] 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.

[19] "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.

[20] 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.

[21] 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.

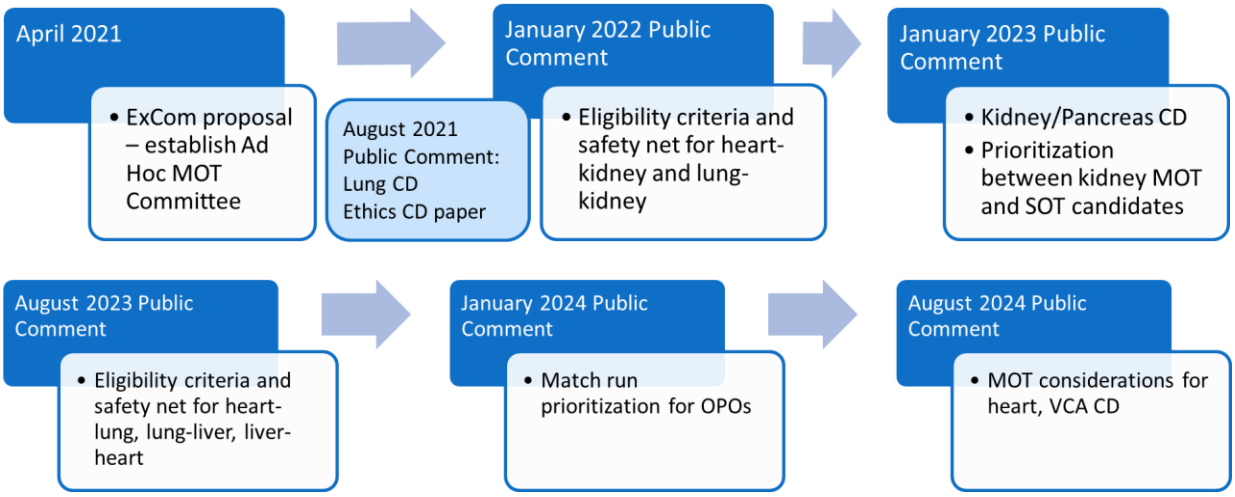
[22] Policy Oversight Committee Meeting Summary, December 9, 2020.

[23] 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.

[24] "Ad Hoc Multi-Organ Transplantation Committee," OPTN, accessed August 3, 2021, https://optn.transplant.hrsa.gov/members/committees/ad-hoc-multi-organ-committee/.

[25] 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.

Figure 1. Proposed Project Map for Ad Hoc Multi-Organ Transplantation Committee[26]



As the OPTN Kidney and Pancreas Transplantation Committees are currently working on proposals to transition the kidney and pancreas allocation systems to a continuous distribution framework,[27] 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.[28]

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** shows the number of pancreas-kidney, liver-kidney, heart-kidney, and lung-kidney transplants performed from 2016 through 2021.[29] The number of transplants increased for each of the four multi-organ combinations during that time. Heart-kidney transplants have more than doubled in recent years, increasing from 140 in 2016 to 349 in 2021. The proportion of simultaneous heart-kidney transplants to all multi-organ transplants involving a kidney has also increased.[30] Simultaneous lung-kidney transplants are rare, with just 15 of these transplants performed in 2021,[31] but the volume has also increased over time. Pediatric heart-kidney and lung-kidney transplants are also rare. There were 22 pediatric heart-kidney transplants performed from 2016-2021 (average of 3.6 per year), and there has only been one pediatric lung-kidney transplant performed since 1988.[32]

[26] 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;* SOT: single-organ transplantation; VCA: vascularized composite allograft

[27] "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.

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

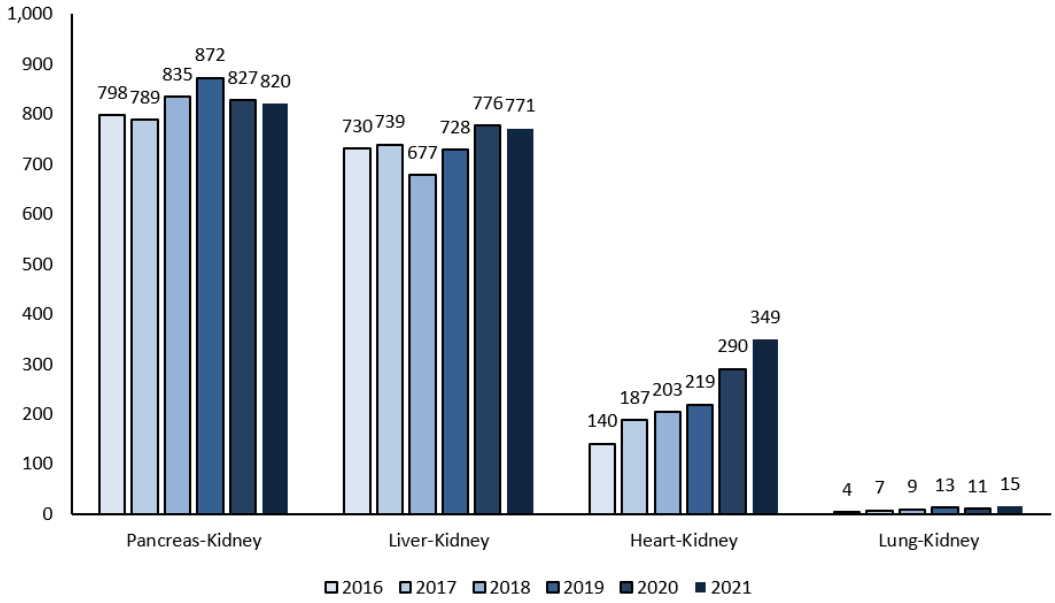
[29] OPTN data as of May 31, 2021. Data shown do not reflect the total volume of transplants performed in the U.S. in this timeframe.

[30] OPTN data as of April 15, 2022. Data shown do not reflect the total volume of transplants performed in the U.S. in this timeframe.

[31] Ibid.

[32] OPTN data as of March 31, 2022.

Figure 2: Number of Multi-Organ Transplants Involving Kidneys, 2016 - 2021[33]



Heart-Kidney Transplantation

For patients that have heart failure as well as declining kidney function, transplant programs must decide whether these patients should be registered 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 transplantation is not recommended for patients with an estimated glomerular filtration rate (eGFR) less than 30 mL/min/1.73m^2.[34] 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.[35] However, multi-organ 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 relative to heart-alone transplantation for patients on dialysis and patients with low GFR prior to transplant.[36,37] Heart-kidney transplant recipients have also shown improved five-year survival compared to heart-alone

[33] 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 April 15, 2022).
[34] 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.
[35] Establish OPTN Requirement for Race-Neutral eGFR Calculations, OPTN Minority Affairs and Kidney Transplantation Committees, January 2022, 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.
[36] 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.
[37] 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.

recipients with renal impairment.[38] 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 poor kidney function may be considered candidates for a subsequent kidney transplant (kidney-after-heart transplant). Such patients – particularly if they have advanced chronic kidney disease – tend to have a greater risk of dying while waiting for a kidney compared to kidney candidates with no previous transplant.[39,40] 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.[41,42] 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,"[43] graft survival should be considered as well as patient survival when determining 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.[44] 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.[45] 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 groups seem to converge around three years post-transplant.[46] 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.[47] 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.[48] Accordingly, the observed patient survival

[38] 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.
[39] 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.
[40] 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.
[41] 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.
[42] Cassuto, "Wait List Death," 2510.
[43] 42 CFR §121.8(a)(5)
[44] 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.
[45] 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.
[46] "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
[47] Lonze, "Kidney Transplantation," 583.
[48] Lonze, "Kidney Transplantation," 583.

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.

Consensus Conference on Heart-Kidney Transplantation

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."[49] 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.[50] A 2014 study noted that while subsequent guidelines removed the 50 mg/mL/min creatinine clearance threshold as a contraindication to lung transplantation,[51] some transplant programs continued not to register candidates for lung transplantation if their GFR was less than 50 mL/min/1.73m^2.[52] The study suggested that this cut-off is reasonable due to adverse outcomes for lung-alone recipients with a GFR below this threshold.[53] 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-alone recipients who require dialysis after transplant.[54] 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.[55]

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

[49] 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.
[50] 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.
[51] 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.
[52] 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.
[53] 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.
[54] 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.
[55] 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/.

transplant,[56] particularly those patients with advanced chronic kidney disease.[57] 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.[58,59] 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.[60,61] 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.[62] A subsequent study also found a survival advantage for lung recipients who received a kidney transplant compared to those who remained on the kidney waiting list, as those who received a kidney transplant were 27% less likely to die.[63]

Purpose

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 purpose of this proposal is to establish eligibility criteria for simultaneous heart-kidney and lung-kidney allocation and to create a safety net for kidney-after-heart and kidney-after-lung allocation. Taken together, eligibility criteria for MOT candidates and safety net policies help to achieve the best use of scarce donor organs.[64]

Proposal for Board Consideration

The Committee proposes establishing eligibility criteria for simultaneous heart-kidney and lung-kidney allocation that adds requirements based on kidney function, similar to the requirements in place for simultaneous liver-kidney allocation, and creating a safety net for kidney-after-heart and kidney-after-lung allocation that is modeled off of the current safety net for kidney-after-liver allocation.

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, the OPO is required to offer the kidney along with the heart or lung to

[56] Srinivas et al., "An Emerging Population," 1883.
[57] Cassuto et al., "Wait List Death," 2509.
[58] Lonze et al., "Kidney Transplantation," 583.
[59] Cassuto et al., "Wait List Death," 2510.
[60] Lonze et al., "Kidney Transplantation," 583.
[61] 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.
[62] Lonze, "Kidney Transplantation," 582.
[63] Osho, "Long-term survival," 8.
[64] "Ethical Implications of Multi-Organ Transplants," Briefing Paper, OPTN, accessed March 29, 2021, https://optn.transplant.hrsa.gov/media/2989/ethics_boardreport_201906.pdf.

transplant candidates who meet the proposed eligibility criteria. The OPO may offer the kidney to heart, lung, or other MOT candidates who do not meet the eligibility criteria, but are not required to do so.

There are three components to the eligibility criteria for when an OPO must offer the kidney along with the heart: (1) heart status, (2) distance from the donor hospital, and (3) kidney function. First, the candidate must be assigned to adult heart status 1, 2, 3, 4, or 5, or any active pediatric heart status. Second, the candidate must be registered for both the heart and kidney at the same transplant hospital located at or within 500 nautical miles (NM) from the donor hospital. Third, the candidate must meet the criteria related to kidney function as outlined in **Table 1**. The candidate must either meet the criteria corresponding to the chronic kidney disease diagnosis, or meet the criteria corresponding to the sustained acute kidney injury diagnosis.

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 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 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 or lung] and a kidney from the same donor.

There are two components to the eligibility criteria for when the OPO must offer the kidney along with the lung: (1) lung composite allocation score, and (2) kidney function. First, the candidate must either have a lung composite allocation score of 28 or greater, or be a pediatric lung candidate (defined as being less than 18 years old when registered on the lung waiting list). Second, the candidate must also be registered for a kidney at the same transplant hospital and meet the criteria related to kidney function outlined in **Table 1**.

The 500 NM distance threshold proposed for the heart-kidney eligibility criteria is consistent with current heart allocation policy and the clarifications to multi-organ allocation policy that were recently implemented. 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.[65] The multi-organ allocation policy implemented in February 2022 extended the distance for multi-organ allocation from 250 NM to 500 NM to better align with these heart allocation policies.[66] There is no proposed distance threshold for the simultaneous lung-kidney eligibility criteria because the lung composite allocation score accounts for distance from the donor hospital as part of the composite score.[67]

Current OPTN policy for SLK precludes pediatric candidates from having to meet eligibility criteria. In other words, pediatric liver-kidney candidates are eligible to receive both the liver and kidney if they are registered for both organs. The Committee's consensus was that pediatric candidates should also be excluded from the medical eligibility criteria for simultaneous heart-kidney and lung-kidney allocation.[68] Accordingly, if an OPO is offering a heart to a pediatric heart-kidney candidate within 500 NM of the donor hospital, and a kidney is available from the same donor, then the OPO must offer the kidney along with the heart. Similarly, if an OPO is offering a lung to a pediatric lung-kidney candidate, and a kidney is available from the same donor, then the OPO must offer the kidney along with the lung.

The Committee's consensus was that it is clinically appropriate to replicate the SLK eligibility criteria based on kidney function for SHK and SLuK so that similar policies address patients with similar needs.[69] The majority of Committee members expressed support for this approach for several reasons.[70] First, it establishes consistency with the SLK policy that has been in place since 2017. The Committee did not find evidence to support 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 Committee 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 medical criteria proposed by the Committee is to exclude the metabolic disease category from the eligibility criteria for SHK and SLuK. The OPTN Lung Committee provided feedback that they were not aware of any lung-kidney transplants due to metabolic disease and recommended removing the category as a result.[71] Similarly, the OPTN Heart Committee was not aware of any heart-kidney transplants performed due to metabolic disease.[72] Public comment feedback supported excluding the metabolic disease diagnosis for heart-kidney and lung-kidney.[73]

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[65] OPTN Policies, accessed January 21, 2022, https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.
[66] "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.
[67] "Establish Continuous Distribution of Lungs," Briefing Paper, OPTN, accessed April 26, 2022, https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf.
[68] Meeting summary for September 20, 2021, meeting, OPTN Ad Hoc Multi-Organ Transplantation Committee, https://optn.transplant.hrsa.gov/media/illjmzt1/20210920_mot_meeting-summary_final.pdf (accessed November 8, 2021).
[69] 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).
[70] 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).
[71] 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).
[72] 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).
[73] "Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation," OPTN, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/establish-eligibility-criteria-and-safety-net-for-heart-kidney-and-lung-kidney-allocation/ (accessed April 12, 2022).

Safety Net

The Committee proposes establishing a safety net for kidney-after-heart and kidney-after-lung allocation in line with current OPTN policy for kidney-after-liver allocation. When the kidney-after-liver safety net was developed, the OPTN Kidney Transplantation Committee had limited data to determine which patients should receive priority for kidney-after-liver transplantation. The Kidney Committee decided to take a conservative approach to the criteria for prioritizing safety net candidates by limiting eligibility to candidates who would qualify for accruing waiting time in kidney-alone allocation.[74] The Kidney Committee planned to monitor the policy following its implementation in 2017 to see if safety net eligibility should be expanded. Two years of monitoring data suggest that the kidney-after-liver safety net has worked well, as there was a significant decrease in waiting list mortality for potentially eligible adult kidney-after-liver candidates following the policy implementation, and a 4-fold increase in the kidney transplant rate for this population.[75]

Because data on kidney-after-heart and kidney-after-lung transplantation is also limited, the consensus of the Committee 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 can be adjusted in the future once the OPTN has collected more data.

Accordingly, the Committee proposes expanding the safety net classification in kidney allocation to include qualifying heart and lung recipients. Qualifying prior lung and heart recipients would receive the same priority in kidney allocation as prior liver recipients through the "Inside Circle Safety Net" classification shown below in **Table 2**.[76] "Inside Circle" refers to a 250 NM circle around the donor hospital.

Table 2: Current Safety Net Priority in Kidney Allocation[77]

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	• 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)

[74] 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).

[75] Wilk et al., "Developing simultaneous liver-kidney transplant medical eligibility criteria," 7.

[76] 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).

[77] "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).

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%
• National (Top 20%) • National (All)			

[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.

Prior heart or lung recipients would qualify for the safety net if they:

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

Patients who received simultaneous heart-kidney or lung-kidney transplants would not be eligible for the safety net unless they experienced immediate and permanent non-function of the transplanted kidney as defined in *OPTN Policy 3.6.B.i*.

Consistent with the kidney-after-liver safety net, prior heart and lung recipients who meet the safety net criteria would remain in the safety net 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 patient would remain at the classification for 30 days from the most recent date of the test or treatment. A patient meeting the criteria for 90 consecutive days, as reported by the transplant program, would remain at the classification until being removed from the waiting list and the program would no longer need to provide updated data.

Based on feedback from the OPTN Lung Transplantation Committee,[78] the 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 OPTN data show that lung recipients with borderline renal function at the time of transplant are registered for a kidney more than 365 days post-transplant.

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%. The Committee proposes giving the same priority to heart 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 Committee acknowledged that this additional limitation would likely improve access to lower KDPI kidneys for kidney-alone candidates.[79] However, the Committee ultimately decided that maintaining consistency, at least initially, with the kidney-after-liver safety net was appropriate. First,

[78] 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).
[79] 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).

there is little to no data regarding the impact of KDPI on outcomes in kidney-after-heart and kidney-after-lung transplantation. Second, consistency with existing policy enables collection of comparative data that could be used to make future policy changes.[80] Finally, there will be additional opportunities to reconsider safety net priority in kidney allocation as kidneys shift to a continuous distribution allocation framework.[81]

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 are 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 at any transplant hospital 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 to consider future policy revisions, if necessary.

Data Collection

The 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.[82] The DAC is an operating committee of the OPTN and oversees all data-related functions, including collaboration with other OPTN committees on modifications, additions, and removals of data elements collected by the OPTN in order to improve the completeness, accuracy, and timeliness of the data.[83] Through discussion, the Committee evaluated each proposed data element against a data quality checklist to ensure the quality, usefulness, transparency and reliability of OPTN data. This checklist is a tool to ensure a consistent and systematic approach to aid OPTN Committees in the assessment of data they seek to add, modify, or remove. The Committee presented their analysis to DAC, which evaluated the potential data burden of the proposal and endorsed the project.[84,85]

The Committee proposes adding new data collection to determine whether candidates meet the eligibility criteria or qualify for the safety net so that those candidates can be given the appropriate priority in organ allocation. Given that the proposed policies for heart-kidney and lung-kidney are similar to existing policies for liver-kidney, the Committee proposes adding data collection similar to what is in place for liver-kidney. The Committee holds that this data collection has worked well for liver-kidney allocation and the kidney-after-liver safety net, and some members of the transplant community are familiar with how this data collection works. Four new data elements would be added to the Heart, Lung, and Heart-Lung candidate registration records in OPTN Waiting List as part of the simultaneous heart-kidney and lung-kidney eligibility criteria, as summarized in the **Appendix**. The data elements would consist of:

[80] Meeting summary for July 26, 2021 meeting, Ad Hoc Multi-Organ Transplantation Committee, https://optn.transplant.hrsa.gov/media/t2bnyygk/20210726_mot_meeting-summary.pdf (accessed December 6, 2021).
[81] "Public comment," OPTN, accessed January 24, 2022, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/.
[82] "Principles for Data Collection," OPTN, accessed April 2, 2021, https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/.
[83] OPTN Data Advisory Committee. https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/
[84] 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.
[85] OPTN Data Advisory Committee, OPTN, Meeting Summary, December 13, 2021, accessed April 15, 2022, https://optn.transplant.hrsa.gov/media/yprejuzq/20211213_optn_dac_meeting_summary.pdf.

- Candidate's diagnosis of either chronic kidney disease (CKD) or sustained acute kidney injury (AKI)
- Medical criteria for CKD diagnosis, including date of diagnosis, and either confirmation of dialysis or the candidate's CrCl or GFR measurements
- Medical criteria for sustained AKI diagnosis, including date of test or treatment, and either confirmation of dialysis or the candidate's CrCl or GFR measurements
- Name of the nephrologist who confirmed the candidate's diagnosis

These data elements are already collected as part of the Liver candidate registration.

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 updating the OPTN Computer System 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 System is already able to determine if kidney candidates received a previous liver transplant and meet safety net criteria. Implementation of this proposal would update the system to determine if a kidney candidate previously received a heart, lung, or heart-lung transplant and should receive the safety net priority, which would be indicated on the Kidney candidate registration.

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. For the eligibility criteria, transplant programs would need to complete at least four additional data fields (diagnosis, qualifying criteria, date, and name of nephrologist). For the safety net, transplant programs would need to ensure that the prior heart, lung, or heart-lung transplant is indicated on the Kidney candidate registration, and would need to complete two additional data fields: (1) date of test or treatment, and (2) medical criteria (dialysis or qualifying eGFR/CrCl). 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.[86]

Overall Sentiment from Public Comment

Committee members presented the proposal to 13 other OPTN committees and to all 11 OPTN regions for feedback, and a video presentation describing the proposal was posted to the OPTN website. Seven professional organizations as well as a number of transplant programs, OPOs, and individuals provided written public comment. The transplant and donation community was generally supportive of this proposal, though a number of comments suggested changes to the eligibility criteria and safety net criteria. The proposal collected sentiment from 247 respondents, including 54 written comments (about 22% of all responses). Sentiment is detailed below in **Figures 3-5**:

[86] "Principles for Data Collection," OPTN, accessed April 2, 2021, https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/.

Figure 3: Volume of Comments by Member Type, Heart-Kidney and Lung-Kidney Proposal, 2022

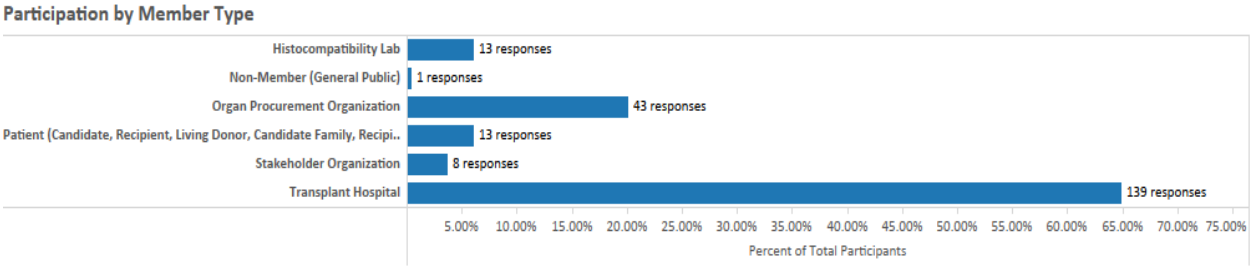
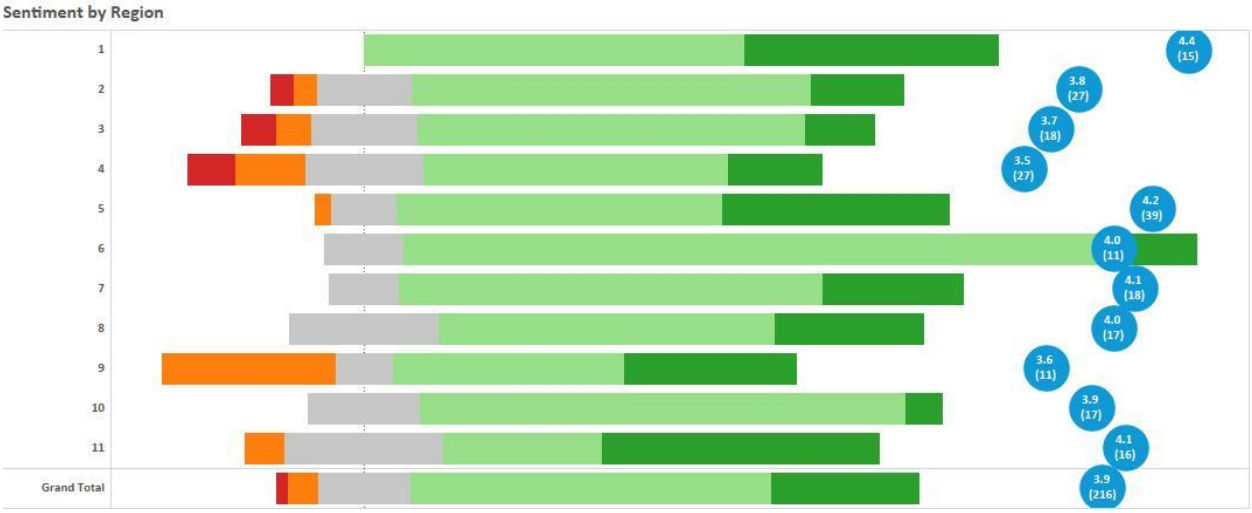
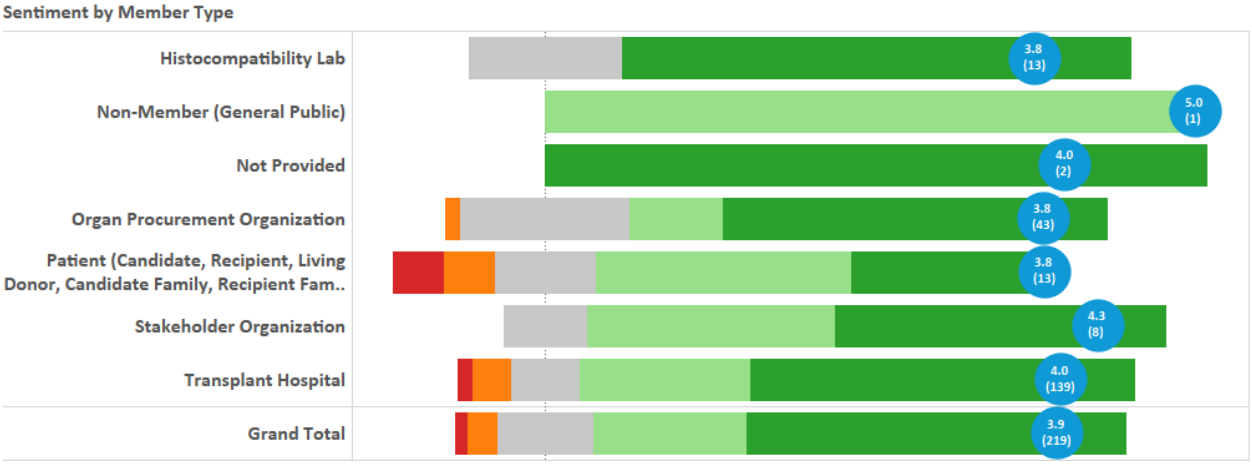


Figure 4: Regional Sentiment, Heart-Kidney and Lung-Kidney Proposal, 2022[87]



There was support for the proposal across all eleven regions, though there were a few respondents who indicated they were opposed or strongly opposed to the proposal in six regions.

Figure 5: Sentiment by Member Type, Heart-Kidney and Lung-Kidney Proposal, 2022[88]



[87] This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). The circles after each bar indicate the average sentiment score and the number of participants in is in the parentheses

[88] Ibid.

There was strong support for the proposal across member types, but a few patients, transplant hospitals, and OPOs indicated opposition to the proposal.

Public comment feedback covered many topics, including overall support for the eligibility criteria and safety net, along with some suggested modifications; considerations for implementation and monitoring of the policy, including concerns about the impact of the proposal on pediatric and adult kidney-alone candidates and minority populations; and recommendations for future policy development.

Feedback: Eligibility Criteria

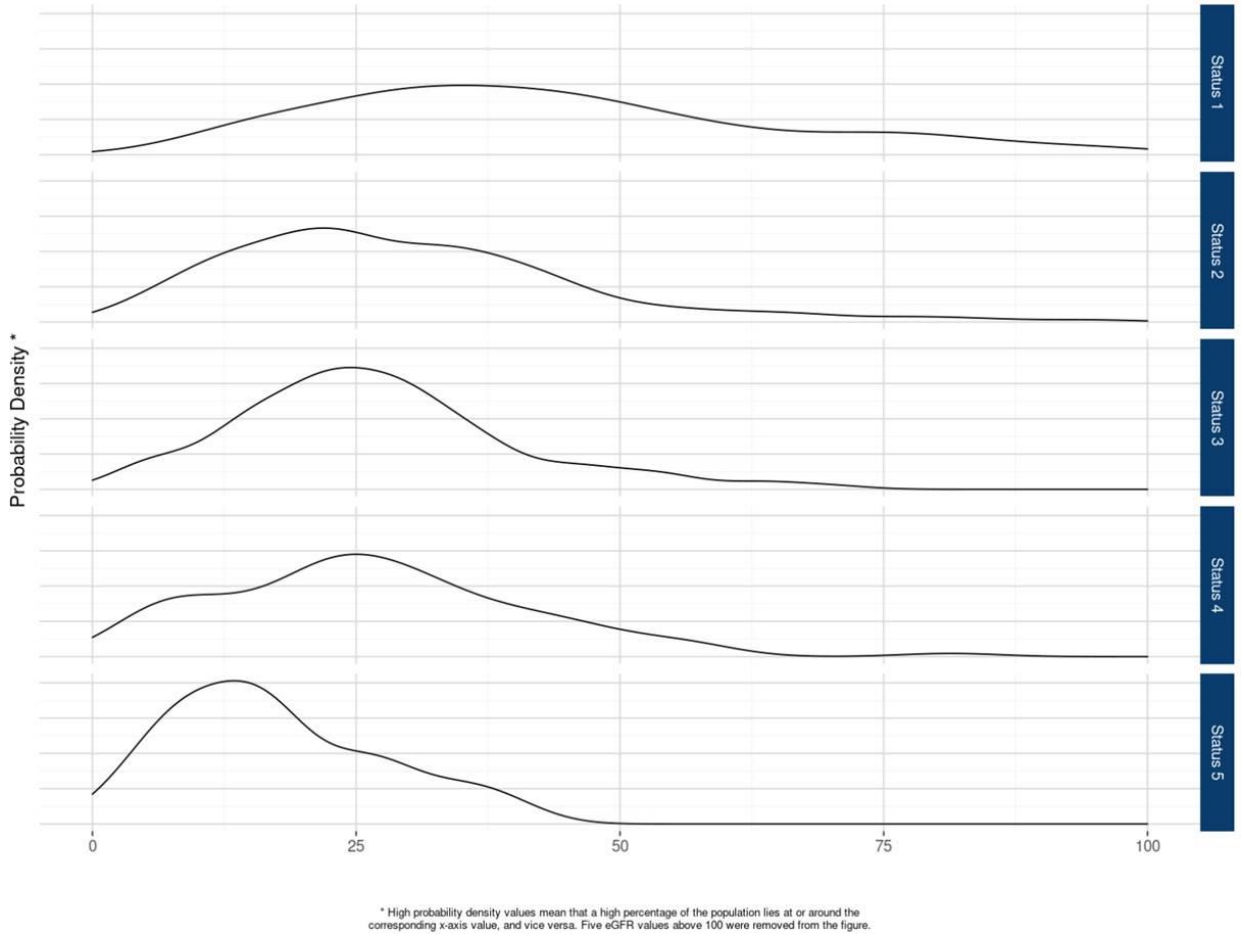
Several comments supported the proposed GFR threshold for the chronic kidney disease diagnosis in the eligibility criteria for heart-kidney and lung-kidney allocation, but a number of comments said that the GFR threshold of less than or equal to 30 mL/min was too low. Respondents suggested raising this threshold to a higher value, with suggestions ranging from 35-50 mL/min. The Committee opted not to change the GFR threshold as the goal is to find a balance between access to transplantation for heart-kidney and lung-kidney candidates, and kidney-alone candidates. While evidence suggests that SHK can proffer a survival benefit to candidates with a GFR between 30-40 mL/min,[89] the small increase in survival benefit relative to heart-alone transplantation must be weighed against the survival benefit that a kidney-alone candidate would gain from access to that kidney. Kidney-alone recipients tend to have higher patient survival than SHK recipients,[90] and about 13 people on average die per day while awaiting kidney transplant.[91] Accordingly, the Committee held that keeping the GFR threshold for the chronic kidney disease diagnosis at less than or equal to 30 mL/min is appropriate.

While the proposal submitted for public comment limited the required shares for heart-kidney candidates to those registered at adult heart status 1, 2, and 3, several comments supported inclusion of the adult status 4 and 5 heart candidates in the eligibility criteria. This change was supported by both the OPTN Heart and Kidney Committees, given evidence that heart candidates who receive dialysis after transplant have worse outcomes.[92] Members of the Kidney Committee noted that they are primarily concerned about SHK transplants being performed for patients with much higher GFRs than would be considered for kidney-alone transplantation, but felt that status 4 and 5 heart candidates should receive offers for a kidney along with the heart as long as the candidates meet the proposed eligibility criteria related to renal function. OPO Committee leadership also supported including the status 4 and 5 candidates in required shares, noting that if they were offering a heart to a status 4 or 5 candidate, then they would be willing to offer a kidney if needed to increase the likelihood of that heart being transplanted. OPO Committee leadership also noted that current policy limits required shares to the status 1, 2, and 3 heart candidates because this criterion also applies to when the OPO must offer the liver along with the heart. Requiring OPOs to offer a liver to heart status 4 and 5 candidates would likely delay liver allocation too much, but OPO Committee leadership did not have the same concerns about allocating kidneys to status 4 and 5 heart candidates. Some members of the MOT Committee were concerned that adding the status 4 and 5 candidates would essentially eliminate the medical severity requirement for heart, while liver-kidney and lung-kidney candidates must still meet medical severity requirements for liver or lung to be eligible for required shares, but ultimately the Committee supported

[89] Brian I. Shaw, Mariya L. Samoylova, Scott Sanoff, et al., "Need for improvements in simultaneous heart-kidney allocation: The limitation of pretransplant glomerular filtration rate," *American Journal of Transplantation* 21 (2021): 2468-2478, DOI: 10.1111/ajt.16466.
[90] Rashikh A. Choudhury, Peter P. Reese, David S. Goldberg, et al., "A Paired Kidney Analysis of Multiorgan Transplantation: Implications for Allograft Survival," *Transplantation* 101 no.2 (2017): 368-376, DOI: 10.1097/TP.0000000000001151.
[91] Based on OPTN data from 2021.
[92] Satoshi Shoji, Toshiki Kuno, Shun Kohsaka, et al., "Incidence and long-term outcome of heart transplantation patients who develop postoperative renal failure requiring dialysis," *The Journal of Heart and Lung Transplantation* 00 (2021) https://doi.org/10.1016/j.healun.2021.11.017.

this change. **Figure 6** shows that Status 5 heart-kidney recipients tend to be transplanted with worse renal function than patients at higher heart statuses, most likely because heart candidates are assigned to Status 5 if they are also registered on the waiting list for at least one other organ and do not qualify for a more urgent heart status. Accordingly, expanding the required shares to include the status 4 and 5 candidates will preserve access to SHK for heart candidates with kidney failure.

Figure 6. Estimated GFR at Transplant for Heart-Kidney Recipients between 1/1/2019 and 5/31/2021 by Heart Status[93]



Feedback: Safety Net

Many comments supported the safety net, indicating that it would help to minimize negative impacts of multi-organ allocation on kidney-alone candidates, and encourage heart and lung transplant programs to proceed with single-organ transplant for patients with borderline renal function. Comments also supported retaining priority for pediatric candidates in kidney allocation over the safety net candidates.

Several comments asked the Committee to ensure that SHK and SLuK recipients would not be eligible for safety net priority so as to protect access to transplantation for kidney-alone candidates. The proposal would only allow SHK or SLuK recipients to qualify for the safety net if the recipients experienced immediate and permanent non-function of the transplanted kidney as defined in *OPTN Policy 3.6.B.i*.

[93] Heart-kidney transplants were excluded from this figure if a third organ was also transplanted. Pediatric heart-kidney transplants were also excluded from this figure.

A few comments suggested incorporating the Estimated Post-Transplant Survival (EPTS) score or a waiting time component into the safety net to balance access to kidney transplantation between safety net candidates and other kidney-alone candidates. The Committee opted to keep the proposal consistent with the kidney-after-liver safety net at this time but will continue to explore approaches to balancing transplant access between multi-organ and single-organ candidates in its future work.

Feedback: Considerations for Implementation and Monitoring

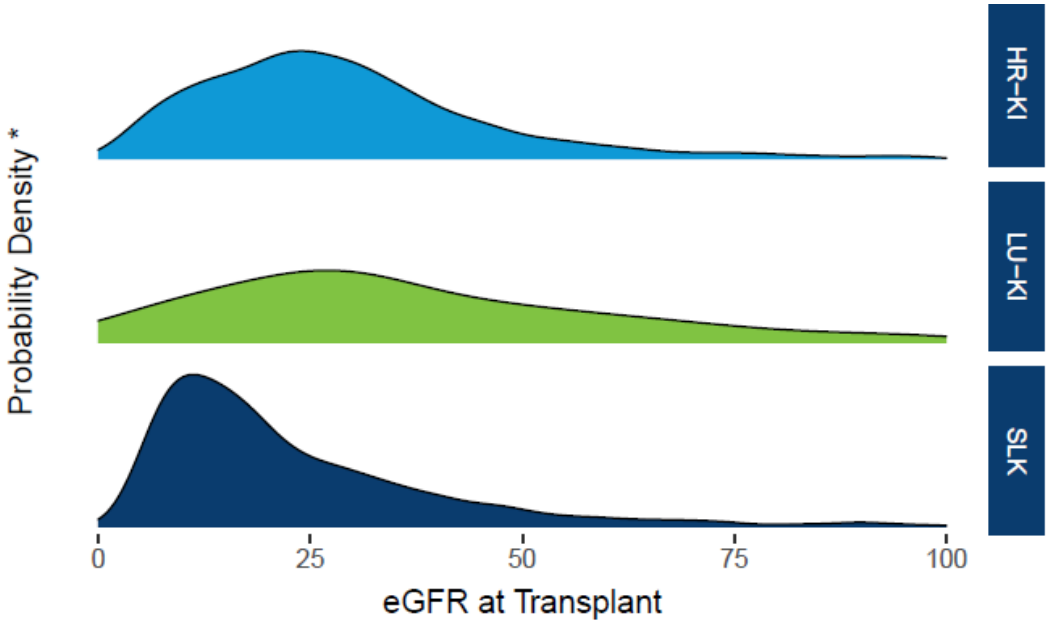
Members voiced concerns that OPOs might be penalized for failing to follow this policy in the event of a late turndown. For example, if a heart is placed with a heart-alone candidate on the match run, and there are no lung-kidney candidates registered, then the OPO would proceed to place the kidneys with other candidates. If the heart is then turned down by the transplant program after the kidneys have been accepted for other candidates, and the next candidate on the heart match run is a heart-kidney candidate, then the OPO would no longer have a kidney available from the same donor to offer along with the heart. In this case, as long as the OPO offers the heart alone to the heart-kidney candidate and does not bypass the heart-kidney candidate completely, then the OPO has complied with policy and will not be referred to the OPTN Membership and Professional Standards Committee (MPSC) for a possible policy violation. The Committee discussed whether to modify the policy language to clarify that if the kidneys have been accepted, then they are no longer "available" to be allocated along with the heart or lungs. The Committee also consulted with OPO Committee leadership, who said that the term "available" is sufficient to account for instances of late turndowns, since OPOs would not rescind the offer on another organ in the event of a late turndown. OPO Committee leadership indicated that it would be helpful to clarify somewhere that "available" means "not already accepted" by another transplant program. The Committee determined that this could be clarified in member education rather than in policy language, particularly since there is an active OPTN workgroup re-evaluating the policy definition of organ offer acceptance.[94]

Some comments requested pre-implementation modeling of this proposal to estimate the impacts of this proposal on various patient populations, including pediatric and adult kidney-alone candidates, highly sensitized candidates, and minority groups. Modeling was not performed as the SRTR's simulated allocation models (SAMs) are not designed to model heart-kidney or lung-kidney allocation and have limited ability to detect minor changes in small populations like multi-organ candidates. This can also be a challenge for modeling the impact of any proposal on pediatric candidates. However, 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 7**). 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.[95] There have not been any concerning declines in pediatric deceased donor kidney transplant volume since SLK

[94] OPTN Operations and Safety Committee, Meeting Summary for March 24, 2022, meeting, Accessed April 26, 2022, https://optn.transplant.hrsa.gov/media/qasggci4/20220324_optn_osc_meeting_summary.pdf.
[95] 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.

policy was implemented in 2017, though other policies that could have impacted kidney transplantation rates were implemented in this time frame as well.[96]

Figure 7: Estimated Glomerular Filtration Rate at Transplant for Heart-Kidney, Lung-Kidney, and Liver-Kidney Recipients from August 10, 2017, to May 31, 2021

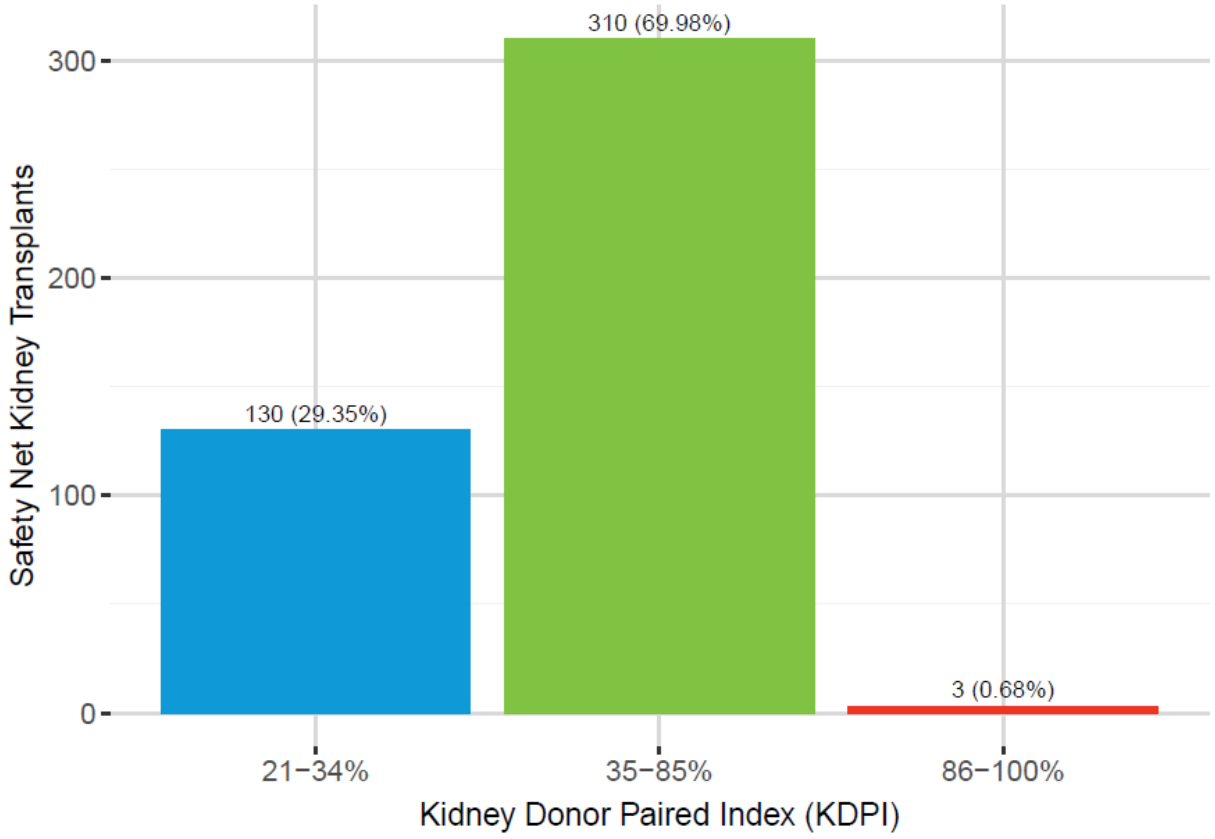


* High probability density values mean that a high percentage of the population lies at or around the corresponding x–axis value, and vice versa. 6 heart–kidney recipients, 1 lung–kidney recipient, and 50 liver–kidney recipients had an eGFR at transplant over 100.

With regard to the quality of kidneys allocated for multi-organ transplantation versus single-organ 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 8**). 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 kidney-after-liver safety net patients who do receive a kidney, the median days between kidney registration and transplant is 109 days.[97]

[96] 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.
[97] Wilk et al., "Developing simultaneous liver-kidney transplant medical eligibility criteria," 3600.

Figure 8. KDPI of Kidneys Allocated Through the Kidney-After-Liver Safety Net from August 10, 2017, to May 31, 2021



Finally, several comments emphasized the importance of robust post-implementation monitoring to assess the impact of the proposal on various populations, including pediatric candidates and minority groups, and requested that outcomes analysis be made available to the public annually. The proposed monitoring plan is detailed later in this paper and includes a number of the metrics suggested via public comment, including transplant outcomes for heart-kidney, lung-kidney, kidney-after-heart, and kidney-after-lung recipients.

Feedback: Recommendations for Future Policy Development

Respondents submitted a number of suggestions for future policy development related to MOT, including considering where multi-organ candidates fit into the allocation sequences relative to single-organ candidates; direction for prioritizing between different categories of multi-organ candidates; establishing review boards or an appeals process for MOT; and collecting additional data to monitor the eligibility criteria and safety net policies. The Committee will consider this feedback as it moves forward with its work.

Compliance Analysis

NOTA and OPTN Final Rule

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,"[98] which "shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate."[99] This proposal impacts allocation as it would create rules to establish when an OPO must offer a kidney along with a heart or lung 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 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:**[100] 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.[101,102]
- **Seeks to achieve the best use of donated organs:**[103] This proposal establishes eligibility criteria for simultaneous heart-kidney and simultaneous lung-kidney allocation based on a candidate's kidney function. 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.[104,105] While the number of simultaneous lung-kidney transplants is small by comparison, some research studies have reported similar survival benefits.[106,107] The intent of this proposal in part is to help ensure that a kidney is only transplanted in conjunction with a heart or lung when needed, so that scarce donor kidneys can otherwise be allocated to kidney-alone or other kidney-MOT candidates.

[98] 42 U.S.C. §274(b)(2)(B).
[99] 42 CFR §121.8(a)(4).
[100] 42 CFR §121.8(a)(1)
[101] 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.
[102] 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.
[103] 42 CFR §121.8(a)(2)
[104] Karamlou et al., "Combined heart-kidney transplant improves post-transplant survival," 456-461.
[105] Kilic et al., "The Survival Benefit of Simultaneous Heart-Kidney Transplantation," 1321-1327.
[106] Yerokun et al., "Simultaneous or Sequential Lung-Kidney Transplantation," S95.
[107] Reich et al., "Combined Lung-Kidney transplantation," 1047-1052.

- **Is designed to avoid futile transplants[108]:** 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.[109,110] 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.[111,112]
- **Is designed to…promote patient access to transplantation[113]:** This proposal gives similarly situated candidates equitable opportunities to receive an organ offer. Currently, required offers for simultaneous heart-kidney and lung-kidney allocation are based on a candidate's proximity to the donor hospital and 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 and lung-kidney allocation helps to ensure that similarly situated candidates have equitable opportunities to receive both organs. The proposed safety net helps to ensure access for 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 current policy, OPOs would be required to offer the kidney to any pediatric heart candidate who is registered for both a heart and a kidney within 500 NM of the donor hospital. 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:[114]** 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.[115]** 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.[116] The proposed eligibility criteria governing simultaneous heart-kidney transplantation requires that a candidate 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.[117,118]

[108] 42 CFR §121.8(a)(5).
[109] Kilic et al., "The Survival Benefit of Simultaneous Heart-Kidney Transplantation," 1324.
[110] Yerokun et al., "Simultaneous or Sequential Lung-Kidney Transplantation," 228.
[111] Lonze et al., "Kidney Transplantation, 582.
[112] Osho et al., "Long-term survival," 8.
[113] 42 CFR §121.8(a)(5).
[114] 42 CFR §121.8(a)(5).
[115] 42 CFR §121.8(a)(8).
[116] 42 CFR §121.8(a).
[117] 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).
[118] 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).

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 candidate's lung composite allocation score[119] and is not altered by this proposal.

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient,[120] and it is specific to various combinations of organ types.[121]

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).[122]

The Final Rule requires the OPTN to "consider whether to adopt transition procedures" whenever organ allocation policies are revised.[123] 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 transition procedures.[124] However, 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' 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 the OPTN Computer System in advance of the implementation date to allow programs to add the new data.

Finally, the Committee submits this proposal under the authority of NOTA, which requires the OPTN to "collect, analyze, and publish data concerning organ donation and transplants,"[125] and the OPTN Final Rule, which requires the OPTN to "maintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors...maintain records of all transplant candidates, all organ donors and all transplant recipients…[and] operate, maintain, receive, publish, and transmit such records and information electronically,"[126] and requires transplant hospitals "as specified from time to time by the Secretary, to submit to the OPTN...information regarding transplantation candidates, transplant recipients, [and] donors of organs…"[127] 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 for required offers, or qualify for the safety net classification in kidney allocation.

OPTN Strategic Plan

Establishing eligibility criteria and safety net policies 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.[128]

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[119] "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.
[120] 42 CFR §121.8(a)(3).
[121] 42 CFR §121.8(a)(4).
[122] 42 CFR §121.8(a)(5).
[123] 42 CFR §121.8(d)(1).
[124] Meeting summary for November 22, 2021 meeting, OPTN Ad Hoc Multi-Organ Transplantation Committee, https://optn.transplant.hrsa.gov/media/meoabhv5/20210816_mot_meeting-summary_final.pdf (accessed April 15, 2022).
[125] 42 U.S.C. §274(b)(2)(I)
[126] 42 CFR §121.11(a)(1)(i)-(iii)
[127] 42 CFR §121.11(b)(2)
[128] "Strategic Plan 2021-2024," OPTN, accessed June 24, 2021, https://optn.transplant.hrsa.gov/media/4632/optn-strategic-plan-2021-2024.pdf.

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

Operations affecting the OPTN

The OPTN is working sequentially to consider continuous distribution allocation systems for deceased donor organs.[129] A proposal to shift allocation of deceased donor lungs to continuous distribution[130] was approved by the OPTN Board of Directors in December 2021.[131] 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,[132] and the OPTN Heart Transplantation Committee is expected to start work to consider continuous distribution of deceased donor hearts in January 2023.[133]

If approved, the OPTN expects to implement the proposed eligibility criteria and safety net after implementation of continuous distribution of lungs but prior to implementation of continuous distribution of kidney and pancreas. Accordingly, the proposed eligibility criteria uses a lung composite allocation score threshold and does not have an associated geographic boundary for lung-kidney allocation, because the composite allocation score accounts for distance. A geographic boundary is proposed for heart-kidney allocation 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 kidney composite allocation score relative to other attributes.[134]

The OPTN will also need to update the OPTN Computer System 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 in OPTN Waiting List that are not presently collected by the OPTN. The OPTN Contractor has agreed that data collected pursuant to the OPTN's regulatory requirements in the OPTN Final Rule will be collected through the Office of Management and Budget (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.

[129] "Continuous Distribution," OPTN, accessed January 24, 2022, https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/.
[130] "Establish Continuous Distribution of Lungs," OPTN, accessed January 24, 2022, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/establish-continuous-distribution-of-lungs/.
[131] "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.
[132] "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.
[133] "Continuous Distribution," OPTN.
[134] "Update on Continuous Distribution of Kidneys and Pancreata," OPTN.

Operations affecting Organ Procurement Organizations

OPOs would need to train staff regarding new allocation policies for simultaneous heart-kidney and lung-kidney transplantation. Required shares will be indicated on the match run.

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. Transplant hospitals may also have to perform additional testing to collect data needed to demonstrate that a candidate meets the eligibility criteria or qualifies for the safety net.

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. This proposal is not expected to have a fiscal impact on histocompatibility laboratories.

Projected Impact on the OPTN

The OPTN Contractor estimates 6,670 hours for implementation. Implementation will involve updates to the OPTN Computer System, as well as providing training and education on the new policy. The OPTN Contractor estimates 250 hours for ongoing support. Ongoing support will involve monitoring to ensure that allocation functions as described in the policy and site surveys. Monitoring reports will be completed six months, one year and two years post-implementation.

Projected Impact on Organ Procurement Organizations

This proposal should not have significant impact on current workflow, but it would require training. 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. It is estimated that the new data collection would add 10-15 minutes of additional data entry time per patient.

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

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."[135] The OPTN will continue to review deceased donor match runs that result in a transplanted

[135] 42 CFR §121.8(a)(7).

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 the OPTN Computer System 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 the OPTN Computer System are consistent with source documentation, including the most recent dates and results for any of the following:

- 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."[136] 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.

[136] 42 CFR §121.8(a)(6).

- 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, and a “safety net” for prior heart or lung transplant recipients who need a kidney transplant. This proposal would require 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.

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. […] signifies language in the current Policies that is not presented here for the purposes of brevity and will not be affected by this proposal.

5.10 Allocation of Multi-Organ Combinations

~~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, 3, 4, or 5, 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.

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.

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.

8.5 Kidney Allocation Classifications and Rankings

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.~~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
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

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:
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
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

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 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
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*	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:
	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		
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

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
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

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:
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
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

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:
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
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

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:
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

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
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

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:
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
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*	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:
	Waiting List, blood type permissible or identical		
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*

Proposed Modifications to OPTN Waiting List Data Collection

Data Element	Form(s)
Diagnosis confirmed by the candidate's transplant nephrologist • Chronic kidney disease • Sustained acute kidney injury	Heart Candidate Record Lung Candidate Record Heart/Lung Candidate Record
Chronic kidney disease • Date • Options to indicate at least one of the following: o Confirmation that the candidate has begun regularly administered dialysis for End Stage Renal Disease (ESRD) o CrCL less than or equal to 30.0 mL/min o eGFR less than or equal to 30.0 mL/min	Heart Candidate Record Lung Candidate Record Heart/Lung Candidate Record
Sustained acute kidney injury • Date of test or treatment • Options to indicate at least one of the following: o Confirmation of dialysis received o CrCL less than or equal to 25.0 mL/min o eGFR less than or equal to 25.0 mL/min	Heart Candidate Record Lung Candidate Record Heart/Lung Candidate Record
Transplant nephrologist confirming candidate's most recent diagnosis for [SHK or SLuK]	Heart Candidate Record Lung Candidate Record Heart/Lung Candidate Record
Date of test or treatment	Kidney Candidate Record *(currently available for liver transplant recipients; will make available for heart and lung transplant recipients)*
Medical criteria to indicate at least one of the following: • Confirmation of dialysis • CrCL less than or equal to 20.0 mL/min • eGFR less than or equal to 20.0 mL/min	Kidney Candidate Record *(currently available for liver transplant recipients; will make available for heart and lung transplant recipients)*

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