

## *Concept Paper*

# Identify Priority Shares in Kidney Multi-Organ Allocation

*OPTN Ad Hoc Multi-Organ Transplantation Committee*

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# Identify Priority Shares in Kidney Multi-Organ Allocation


*Sponsoring Committee:* Ad Hoc Multi-Organ Transplantation  
*Public Comment Period:* January 19, 2023 – March 15, 2023

## Executive Summary

The Ad Hoc Multi-Organ Transplantation Committee aims to establish an updated framework for kidney multi-organ allocation to improve equity in access to transplant between single organ and multi-organ candidates, and to improve efficiency in allocating multiple organ types from one donor. This framework will consider:

- If and when kidneys should be offered to kidney-alone candidates prior to kidney multi-organ candidates
- How to determine which kidney (including laterality) should be offered to various kidney multi-organ and single organ candidates, many of whom have equal priority for offers in current policy
- How to handle situations in which organ offer acceptance conflicts with a multi-organ offer required by policy
- Providing more direction for multi-organ allocation while leaving flexibility for the dynamics of the allocation process

The purpose of this concept paper is to introduce ideas and request feedback from the community to inform a future policy proposal.



# Background

OPTN policies have historically required organ procurement organizations (OPOs) to allocate multiple organs from the same donor to multi-organ candidates meeting certain criteria, prior to allocating individual organs to single organ candidates. The intent of these policies is to promote access to transplant for candidates experiencing failure in multiple organs, since (1) it can be harder for candidates to find a good match with two or more organs from the same donor,<sup>1</sup> and (2) receiving organs from the same donor instead of from different donors may reduce the level of the candidate's immune system response and lower the risk that their body will reject the organs.<sup>2</sup> However, given the scarcity of organs, allocating more than one organ to a single candidate must be weighed against the opportunity to allocate lifesaving organs to multiple potential transplant recipients. Such equity concerns must also be balanced against considerations for efficient allocation of multiple organ types from one donor.

## Equity in Access to Transplant

Ethical considerations related to multi-organ allocation were examined in a 2019 OPTN white paper, *Ethical Implications of Multi-Organ Transplants*.<sup>3</sup> The paper noted that "MOT allocation could have the potential adverse effects of redirecting high-quality organs that are consequently unavailable to single organ candidates" and included the following recommendations:

- The system for allocation of organs for MOT candidates should be based on the ethical principles of equity and utility, be transparent, and be consistent across the different organ combinations unless there is an ethical justification for a different system
- Allocation policies should prioritize MOT candidates who have medical urgency in both organs, but generally should not prioritize MOT candidates who do not have medical urgency in one organ

In alignment with these recommendations, policies for kidney multi-organ allocation place limits on when multiple organs must be offered to a single candidate. These limits are based on medical urgency, distance, and clinical criteria regarding kidney function, as summarized in **Table 1**. Eligibility criteria for when an OPO must offer a kidney along with a liver were implemented in 2017.<sup>4</sup> Similar requirements for heart-kidney and lung-kidney allocation were approved by the OPTN Board of Directors in June 2022 and are pending implementation.<sup>5,6</sup>

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<sup>1</sup> Donation rates vary by organ and are highest for kidneys, followed by liver, heart, lung, and pancreas, which means that some donors will not be able to donate all of the organs that a multi-organ candidate needs. See OPTN/SRTR 2020 Annual Data Report. Published 2022. Accessed December 2, 2022. [http://srtr.transplant.hrsa.gov/annual\\_reports/Default.aspx](http://srtr.transplant.hrsa.gov/annual_reports/Default.aspx). For donors that are able to donate multiple organs, there may be other organ-specific reasons why one of the organs would not be a good match for a certain multi-organ candidate, e.g., biopsy results unacceptable or organ anatomical damage or defect. See "Update to Refusal Codes," OPTN, Notice of Changes to OPTN Data Collection, accessed December 2, 2022, [https://optn.transplant.hrsa.gov/media/4695/update\\_to\\_refusal\\_codes\\_june\\_2021\\_policy\\_notice.pdf](https://optn.transplant.hrsa.gov/media/4695/update_to_refusal_codes_june_2021_policy_notice.pdf).

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

<sup>3</sup> "Ethical Implications of Multi-Organ Transplants," OPTN, White Paper, accessed November 3, 2022, [https://optn.transplant.hrsa.gov/media/2989/ethics\\_boardreport\\_201906.pdf](https://optn.transplant.hrsa.gov/media/2989/ethics_boardreport_201906.pdf).

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

<sup>5</sup> Board of Directors Executive Summary, OPTN, June 27, 2022, accessed November 3, 2022, [https://optn.transplant.hrsa.gov/media/hv3p3alg/20220627\\_board-of-directors\\_executive-summary.pdf](https://optn.transplant.hrsa.gov/media/hv3p3alg/20220627_board-of-directors_executive-summary.pdf).

<sup>6</sup> "Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation," OPTN, Notice of OPTN Policy Changes, accessed

**Table 1. Requirements for Offering a Kidney with Another Organ**

Organ combination	Medical urgency requirement	Clinical criteria regarding kidney function
Liver-kidney	Liver Status 1A or 1B within 250 NM <sup>7</sup> Liver MELD or PELD $\geq$ 29 within 250 NM Liver MELD or PELD $\geq$ 15 within 150 NM	Diagnosis of chronic kidney disease or sustained acute kidney injury and either be on dialysis or meet GFR/CrCL threshold, OR diagnosis of metabolic disease
Heart-kidney	<b>Current policy:</b> Heart Adult Status 1, 2, 3 or any active pediatric heart status within 500 NM  <b>Approved but not yet implemented policy:</b> Heart Adult Status 1, 2, 3, 4, or 5 or any active pediatric heart status within 500 NM	<b>Current policy:</b> N/A  <b>Approved but not yet implemented policy:</b> Diagnosis of chronic kidney disease or sustained acute kidney injury and either be on dialysis or meet GFR/CrCL threshold
Lung-kidney	<b>Current policy:</b> Lung allocation score of $\geq$ 35 or lung candidates < 12 years old  <b>Approved but not yet implemented policy:</b> Lung composite allocation score $\geq$ 25 or < 18 years old when registered on the lung waiting list	<b>Current policy:</b> N/A  <b>Approved but not yet implemented policy:</b> Diagnosis of chronic kidney disease or sustained acute kidney injury and either be on dialysis or meet GFR/CrCL threshold
Pancreas-kidney	Diagnosed with diabetes or have pancreatic exocrine insufficiency with renal insufficiency	No additional criteria for required shares but pancreas-kidney candidates must meet the same criteria as kidney-alone candidates in order to accrue waiting time

Despite these restrictions on required kidney multi-organ allocation, research suggests that kidney-alone transplant candidates may be disadvantaged by these policies.<sup>8</sup> A recent study analyzed match run data for donors who had both kidneys recovered, where one kidney was allocated to a multi-organ recipient and one kidney was allocated to a kidney-alone or simultaneous pancreas-kidney recipient.<sup>9</sup> The analysis compared outcomes between the multi-organ recipient, the kidney-alone or pancreas-kidney recipient, and the next candidate on the kidney match run who would have received the organ offer if the first kidney had not gone to a multi-organ recipient. The analysis found a higher mortality risk for those next-sequential candidates relative to patients who received a kidney-alone or simultaneous pancreas-kidney transplant, as shown in **Figure 1**.<sup>10</sup>

November 3, 2022, [https://optn.transplant.hrsa.gov/media/erucde2m/policy-notice\\_est-elgbly-crit-and-safety-for-hrt-kid-and-lung-kid-alloc\\_mot.pdf](https://optn.transplant.hrsa.gov/media/erucde2m/policy-notice_est-elgbly-crit-and-safety-for-hrt-kid-and-lung-kid-alloc_mot.pdf).

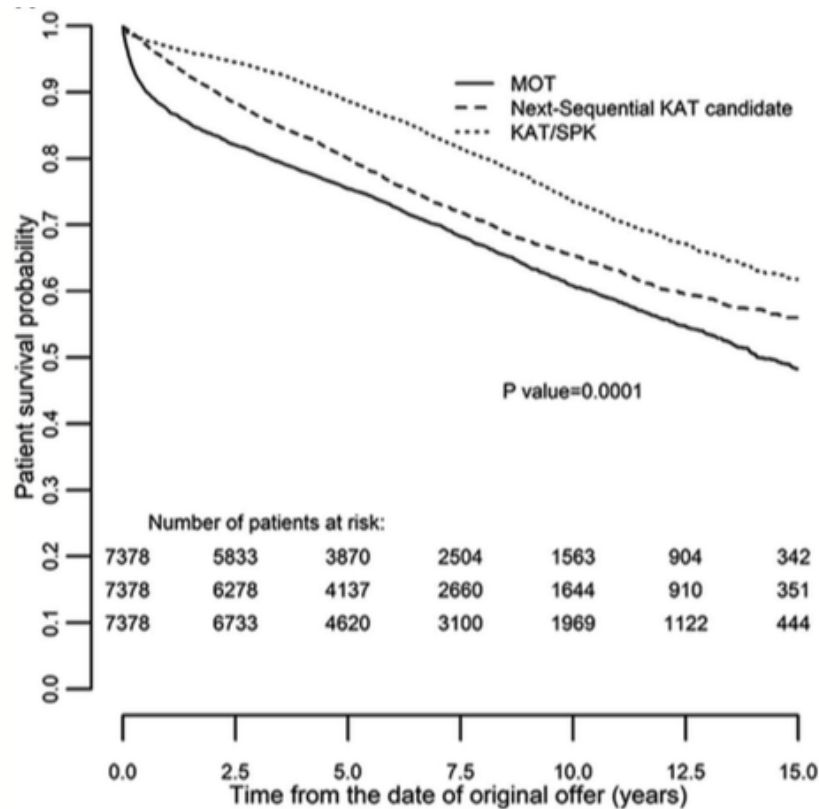
<sup>7</sup> The Committee has a policy proposal out for public comment this cycle which would expand required SLK shares out to 500 NM for candidates with MELD of 29 or greater, Status 1A, or Status 1B. See <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/expand-required-simultaneous-liver-kidney-allocation/>.

<sup>8</sup> Scott G. Westphal, Eric D. Langewisch, Amanda M. Robinson, et al., "The impact of multi-organ transplant allocation priority on waitlisted kidney transplant candidates," *American Journal of Transplantation* no. 6 (2021): 2161-2174, DOI: 10.1111/ajt.16390.

<sup>9</sup> Ibid.

<sup>10</sup> Ibid.

Figure 1. Overall Patient Survival From the Time of the Original “Next-Sequential” Offer<sup>11</sup>



Related concerns about the impact of multi-organ allocation on kidney-alone candidates have been noted via public comment feedback on several OPTN policy proposals,<sup>12,13,14</sup> with particular concern regarding the impact on pediatric kidney candidates and highly sensitized kidney candidates.<sup>15</sup> The OPTN Pediatrics Committee also previously explored this topic and found that in instances in which one kidney was transplanted in a multi-organ candidate and the other kidney was transplanted in a pediatric kidney candidate, the age of the next candidate on the match run was less than 18 years old 63% of the time (**Figure 2**). Those pediatric candidates would have been offered a kidney had it not already been accepted for a multi-organ candidate.

<sup>11</sup> Westphal et al., “The impact of multi-organ transplant allocation priority,” 2171. MOT = multi-organ transplant recipient; KAT = kidney-alone transplant recipient; SPK = simultaneous pancreas-kidney transplant recipient.

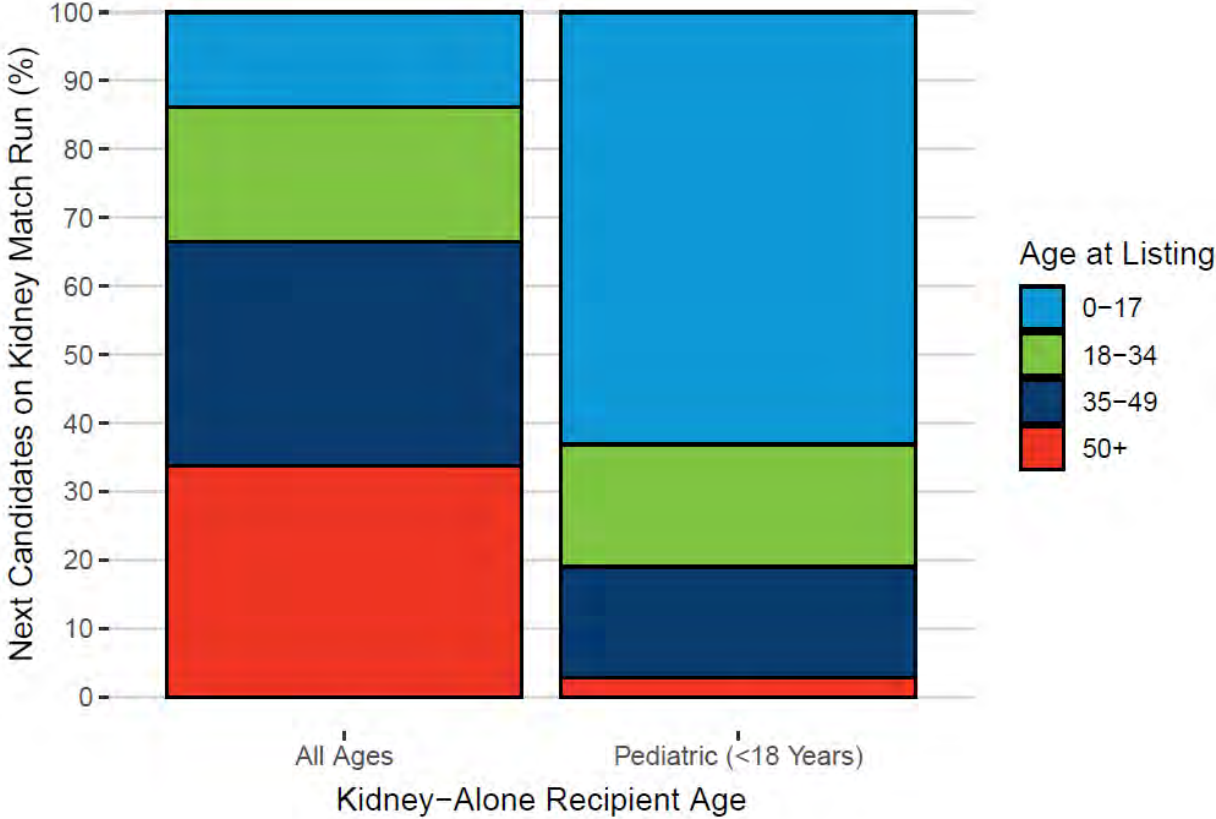
<sup>12</sup> “Clarify Multi-Organ Allocation Policy,” OPTN, accessed November 3, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/clarify-multi-organ-allocation-policy/>.

<sup>13</sup> “Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation,” OPTN, accessed November 3, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/establish-eligibility-criteria-and-safety-net-for-heart-kidney-and-lung-kidney-allocation/>.

<sup>14</sup> “Update Multi-Organ Allocation for Continuous Distribution of Lungs,” OPTN, accessed November 3, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/update-multi-organ-allocation-for-continuous-distribution-of-lungs/>.

<sup>15</sup> “Continuous Distribution of Kidneys and Pancreata Update,” OPTN, accessed November 3, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/continuous-distribution-of-kidneys-and-pancreata-update/>.

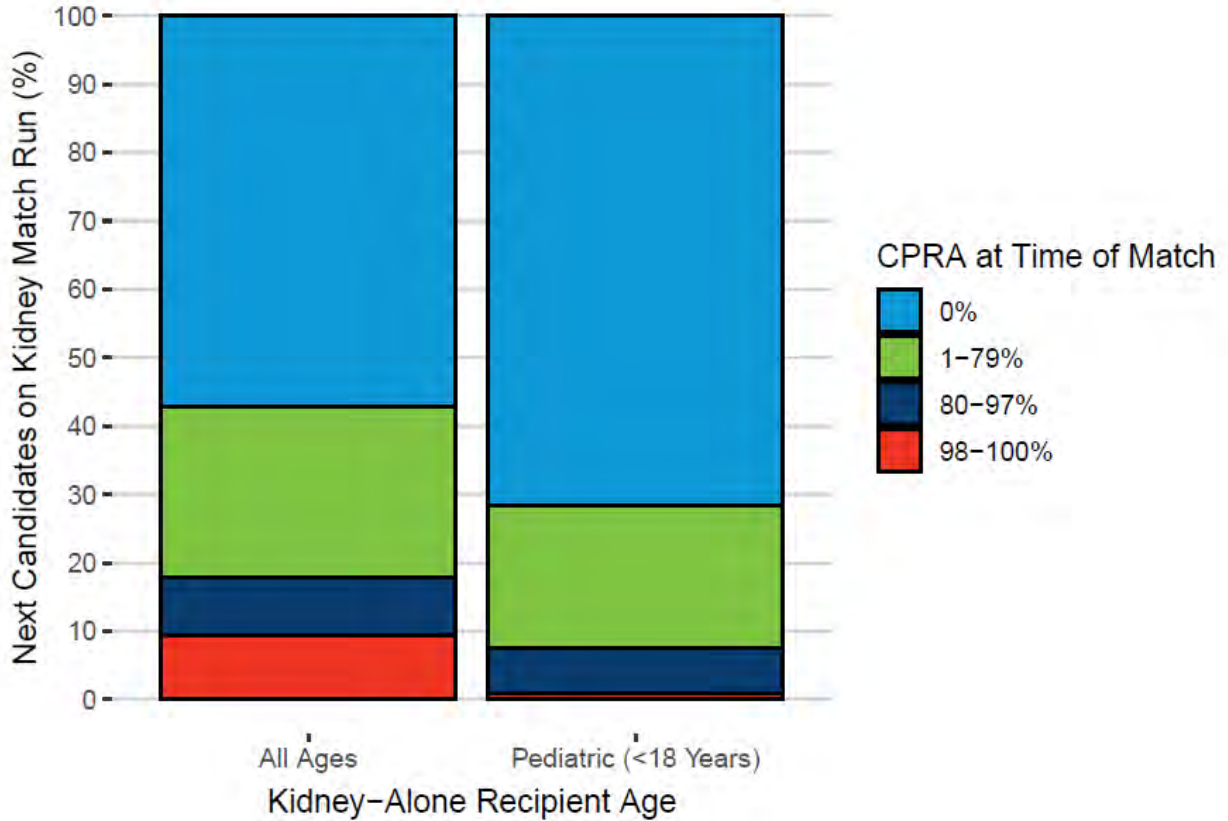
**Figure 2. Age at Listing for Next Candidates on the Kidney Match Run by Kidney-Alone Recipient Age, 2017 – 2019<sup>16</sup>**



The analysis completed for the Pediatrics Committee also evaluated the CPRA at the time of the match for the next sequential candidate on the match run, as shown in **Figure 3**. While the CPRA at time of match for the next candidate on the match run was often 0%, there were 373 out of 3,955 cases where the next candidate on the match run had a CPRA of 98-100%.

<sup>16</sup> "Examining Kidney Priority for Multi-Organ Candidates Compared to Pediatric Kidney-Alone Candidates," OPTN, Descriptive Data Request for OPTN Pediatric Transplantation Committee, December 16, 2020.

**Figure 3: CPRA at Time of Match for Next Candidates on the Kidney Match Run by Kidney-Alone Recipient Age, 2017-2019<sup>17</sup>**



Public comment feedback<sup>18</sup> and journal articles<sup>19,20</sup> have also expressed concerns that multi-organ allocation tends to pull kidneys of higher quality (as indicated by lower Kidney Donor Profile Index, or

<sup>17</sup> "Examining Kidney Priority for Multi-Organ Candidates Compared to Pediatric Kidney-Alone Candidates," OPTN.

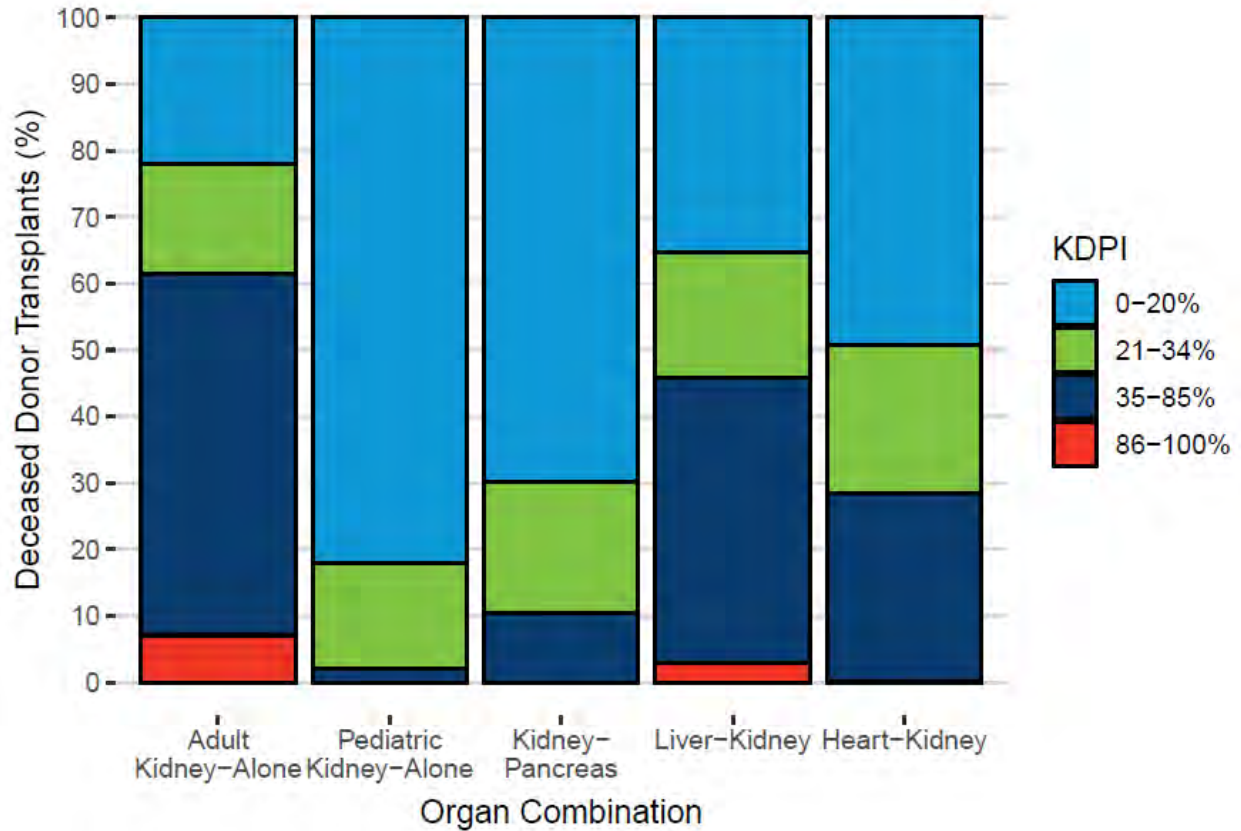
<sup>18</sup> "Clarify Multi-Organ Allocation Policy," OPTN, accessed November 3, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/clarify-multi-organ-allocation-policy/>.

<sup>19</sup> Westphal et al., "The impact of multi-organ transplant allocation priority," 2162.

<sup>20</sup> S. Ali Husain, Kristen L. King, Geoffrey K. Dube, et al., "Regional Disparities in Transplantation With Deceased Donor Kidneys With Kidney Donor Profile Index Less Than 20% Among Candidates With Top 20% Estimated Post Transplant Survival," *Progress in Transplantation* no. 29 (2019) 4: 354-360, DOI: 10.1177/1526924819874699.

KDPI) away from kidney-alone candidates, as shown in **Figure 4**. A higher percentage of multi-organ transplants involving kidneys have low KDPIs than adult kidney-alone transplants.

**Figure 4. Percent of Deceased Donor Transplants by Organ Combination and KDPI, 2017-2019<sup>21</sup>**



As noted in the OPTN white paper *Ethical Implications of Multi-Organ Transplants*,<sup>22</sup> equity in access to transplant should also be balanced with utility. Multi-organ recipients tend to have worse kidney graft survival, as shown in **Figure 5**, and kidney-alone recipients tend to live longer post-transplant.<sup>23</sup>

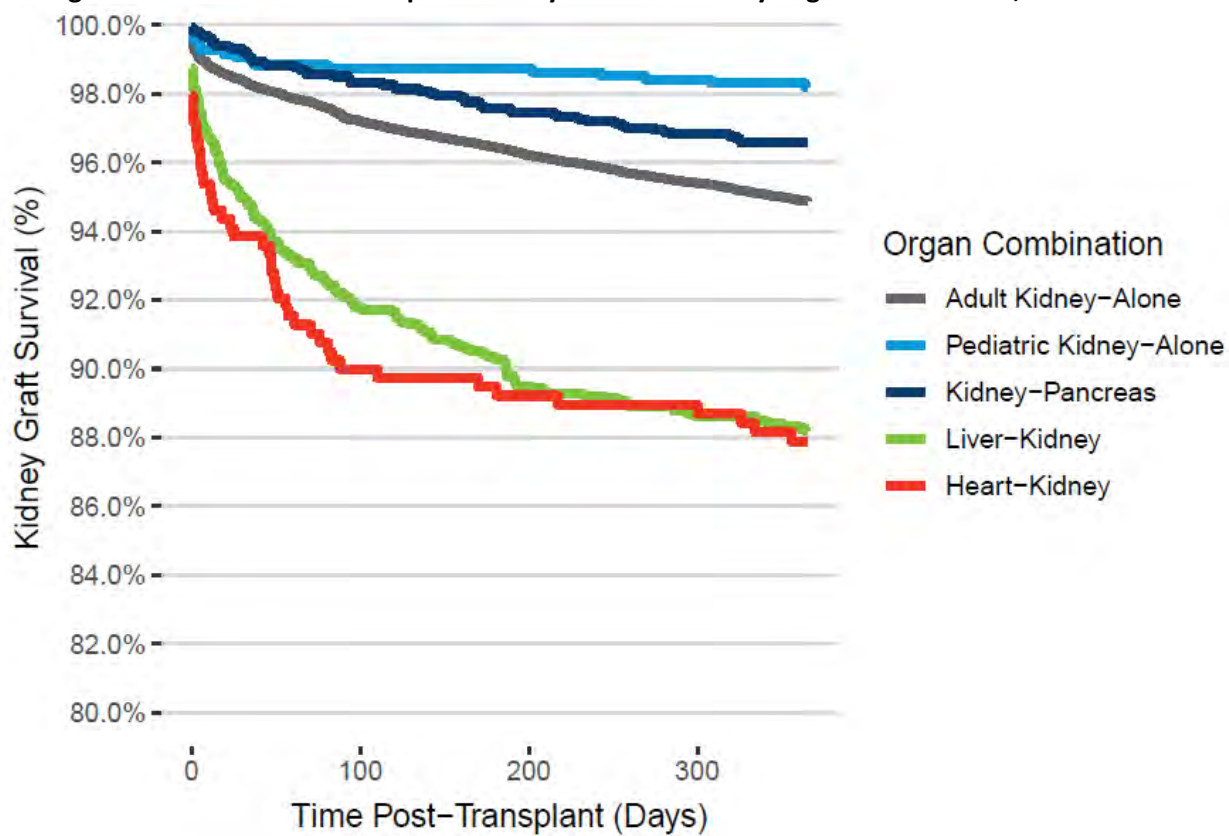
<sup>21</sup> Ibid.

<sup>22</sup> "Ethical Implications of Multi-Organ Transplants," OPTN, White Paper, accessed November 3, 2022, [https://optn.transplant.hrsa.gov/media/2989/ethics\\_boardreport\\_201906.pdf](https://optn.transplant.hrsa.gov/media/2989/ethics_boardreport_201906.pdf).

<sup>23</sup> Rashikh A. Choudhury, Peter P. Reese, David S. Goldberg, et al., "A Paired Kidney Analysis of Multiorgan Transplantation: Implications for Allograft Survival," *Transplantation* no. 101 (2017): 368-376.



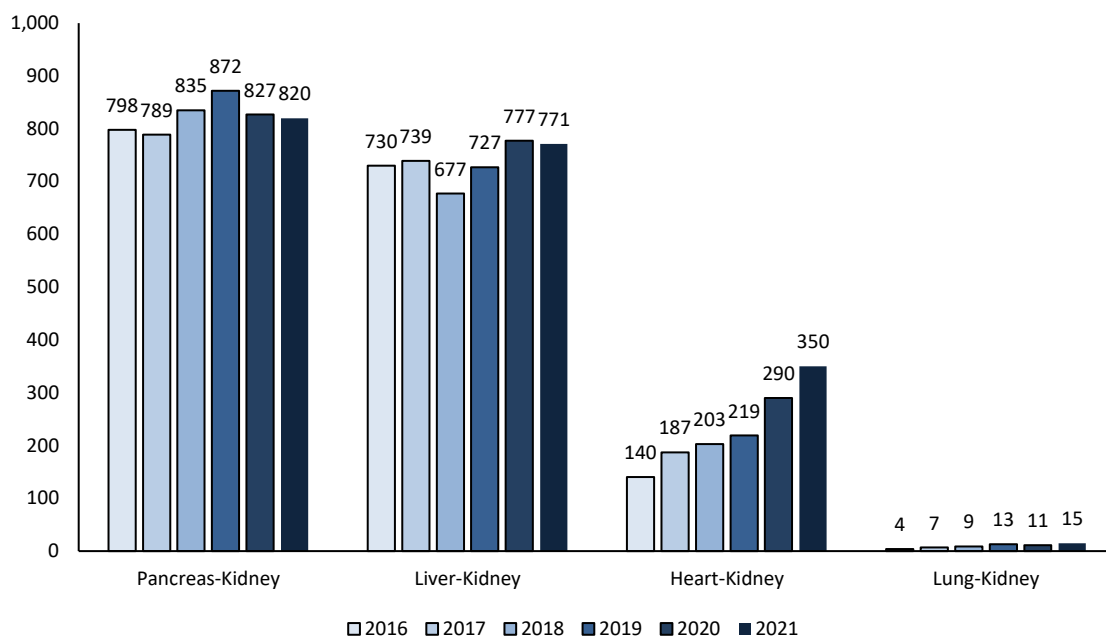
**Figure 5. One-Year Post Transplant Kidney Graft Survival by Organ Combination, 2017-2018<sup>24</sup>**



At the same time, the frequency of kidney multi-organ transplants is increasing, as shown in **Figure 6**.

<sup>24</sup> "Examining Kidney Priority for Multi-Organ Candidates Compared to Pediatric Kidney-Alone Candidates," OPTN.

**Figure 6: Number of Multi-Organ Transplants Involving Kidneys, 2016 - 2021<sup>25</sup>**



However, while the overall number of kidney multi-organ transplants is growing, it is growing at a lower rate than kidney-alone transplantation, as shown in **Table 2**.

**Table 2: Percentage of Total Kidney Transplants that were Multi-Organ Transplants, 2016 - 2021<sup>26</sup>**

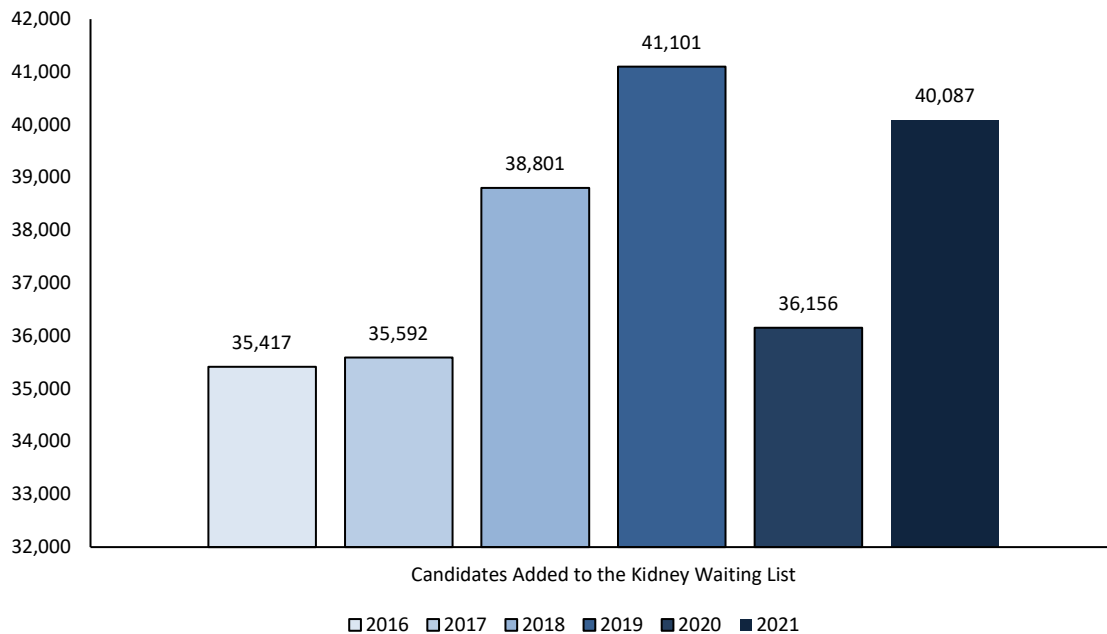
Transplants by Year	2016	2017	2018	2019	2020	2021
Total number of kidney multi-organ transplants performed	1,679	1,725	1,731	1,843	1,912	1,964
Percentage of total kidney transplants that were multi-organ transplants	11.8%	11.6%	11.1%	10.6%	10.4%	10.1%

Kidney waiting list additions have also been growing, aside from a dip in registrations during the COVID-19 pandemic (see **Figure 7**).

<sup>25</sup> OPTN data as of November 2, 2022.

<sup>26</sup> OPTN data as of January 13, 2023. This table includes pancreas-kidney transplants and kidney multi-organ transplants involving more than two organs (e.g. kidney-liver-intestine transplants) as kidney multi-organ transplants.

**Figure 7. Number of Candidates Added to the Kidney Waiting List, 2016 - 2021<sup>27</sup>**



Taken together, these data show increasing need for a limited number of donor kidneys among both kidney multi-organ and single-organ candidates, which underscores the importance of assessing whether current kidney multi-organ policies achieve the OPTN’s goals of balancing equity and utility in access to transplant.

## Efficiency in Multi-Organ Allocation

In addition to equity considerations, public comment feedback has also included concerns about the clarity of multi-organ policies and the efficiency of multi-organ allocation.<sup>28,29</sup> The OPTN Computer System has eight different match runs that OPOs use to offer organs: heart, lung, heart-lung, liver, intestine, pancreas/kidney-pancreas, kidney, and VCA. OPOs must offer organs in the order that candidates are listed on each match run, but have discretion to decide the order in which they work through the various match runs. The policies that require an OPO to offer a kidney along with a heart, lung, or liver carry equal weight, and the policies do not indicate which candidate should take priority. Accordingly, when OPOs have a multi-organ donor, they may have more than two candidates who meet the criteria for required multi-organ shares but only two kidneys to allocate. For example, if the first candidates on the liver, heart, and lung match runs all require a kidney and meet policy criteria for a required share, the OPO must decide how to allocate the two kidneys from a donor among those three candidates. Because OPOs have discretion on how to handle these cases, this can lead to inconsistency as to whether similarly situated candidates receive organ offers, and can lead to inefficiency in allocation for OPOs as they work through allocating kidneys between multiple priority candidates. If an OPO is

<sup>27</sup> Ibid.

<sup>28</sup> “Clarify Multi-Organ Allocation Policy,” OPTN.

<sup>29</sup> “Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation,” OPTN.

offering both a right and left kidney, policy also does not provide any direction on laterality in terms of which candidate should receive the right or left kidney.

Finally, policy does not explicitly state what OPOs should do if a required share conflicts with an organ offer acceptance. For example, an OPO may place a heart with a heart-alone candidate and the kidneys with other candidates, but then receive notification that the heart candidate can no longer accept the organ. If the next candidate on the list is a qualifying heart-kidney candidate, policy says that the OPO must offer the kidney along with the heart, but the OPO no longer has a kidney to offer since the kidneys were accepted by other candidates. OPO members have expressed concern that in these situations, they are not clear on the appropriate action to take in order to comply with OPTN policies.<sup>30</sup>

## Project Plan

The Ad Hoc Multi-Organ Transplantation Committee (Committee) is working on a project to establish an updated framework for kidney multi-organ allocation to improve equity in access to transplant between kidney-alone and kidney multi-organ candidates, and to improve efficiency in allocating multiple organ types from one donor. This framework will consider:

- If and when kidneys should be offered to kidney-alone candidates prior to kidney multi-organ candidates
- How to determine which kidney (including laterality) should be offered to various kidney multi-organ and single-organ candidates, many of whom have equal priority for offers in current policy
- How to handle situations in which organ offer acceptance conflicts with a multi-organ offer required by policy
- Providing more direction for multi-organ allocation while leaving flexibility for the dynamics of the allocation process

The goal of this concept paper is to introduce ideas and request feedback from the community to inform a future policy proposal. The timing of a future policy proposal may depend on the timing of the project to establish continuous distribution of kidneys and pancreata.<sup>31</sup> This project would be implemented at the same time as, or following, implementation of continuous distribution of kidneys and pancreata, so required kidney-alone shares would need to be defined in a way that is consistent with the continuous distribution allocation framework. For example, required kidney-alone shares could be defined based on a composite allocation score threshold. Accordingly, when this project goes to public comment may depend on when the MOT Committee has enough information on the kidney composite allocation score (CAS) to potentially define a kidney CAS threshold. Furthermore, if this project would require kidney-alone shares prior to allocating organs to kidney-pancreas candidates, that could impact how kidney-pancreas allocation is modeled for continuous distribution of kidneys and pancreata and may require additional simulation modeling.

In order to improve the efficiency of multi-organ allocation, a future policy proposal may also consolidate multi-organ policies into one policy to clarify the workflow for OPOs in terms of whether certain required shares take priority over other required shares. Such changes may include more direction for OPOs on how to work through the various organ match runs.

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<sup>30</sup> "Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation," OPTN, accessed November 3, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/establish-eligibility-criteria-and-safety-net-for-heart-kidney-and-lung-kidney-allocation/>.

<sup>31</sup> "Continuous distribution – kidney and pancreas," OPTN, accessed November 4, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/continuous-distribution-kidney-and-pancreas/>.

## Progress So Far

Overall, the Committee supports a more nuanced approach to prioritizing kidney multi-organ and kidney-alone candidates to provide access to transplant for medically urgent multi-organ candidates without disproportionately disadvantaging kidney-alone candidates. The Committee recognizes that it is challenging to compare different candidate populations in terms of medical urgency while also providing access to transplant for all candidates. The Committee notes that some single-organ candidates may have a higher ethical claim to an organ – for example, a highly sensitized kidney-alone candidate who will not get another offer, compared to a liver-kidney candidate with relatively low medical urgency – but multi-organ candidates have generally been prioritized by OPTN policies due to higher risk of dying on the waiting list.

The Committee requests community feedback on the following approaches to improve equity in access to transplant between kidney-alone and kidney multi-organ candidates:

- Required kidney shares
- Limit kidney multi-organ allocation

The Committee also requests feedback on the following topics related to improving the efficiency of multi-organ allocation:

- Determining how to offer kidneys (including laterality) among candidates of equal priority in current policy
- Situations in which organ offer acceptance conflicts with a multi-organ offer required by policy
- Providing more direction for multi-organ allocation while leaving flexibility for the dynamics of the allocation process

The Committee's discussions on these topics are outlined in more detail below.

## Required Kidney Shares

One approach to improve access to transplantation for kidney-alone candidates would be to categorize kidney multi-organ candidates by priority and incorporate them into the kidney allocation sequence.<sup>32</sup> However, current multi-organ policies require OPOs to offer kidneys off of other organ match runs before offering kidneys on the kidney match run, so this approach would require changing policy to direct the OPO to offer organs off of the kidney match run first.

A more limited approach would be to require OPOs to offer the kidney alone to certain candidates on the kidney match run prior to allocating a kidney to a multi-organ candidate on another match run. The Committee identified the following groups of kidney candidates who may warrant priority for offers over candidates who are listed for a kidney as well as a heart, liver, or lung:

- Highly sensitized kidney candidates
- Medically urgent kidney candidates
- Candidates needing more than two organs
- Kidney-pancreas candidates
- Pediatric kidney candidates

The Committee noted that these candidates could essentially be divided into two groups: (1) candidates who are not likely to get another offer (highly sensitized and medically urgent candidates), and (2)

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<sup>32</sup> Xingxing S. Cheng and Peter P. Reese, "Incorporating kidney-related multi-organ transplants into the kidney allocation sequence," *American Journal of Transplantation* no. 21 (2021): 2614-2615, DOI: 10.1111/ajt.16542.

candidates who get priority for high quality/low KDPI kidneys in the current allocation system (kidney-pancreas and pediatric candidates). Different solutions may be appropriate to balance access to transplantation for these different populations.

### Highly Sensitized Kidney Candidates

Current kidney allocation policy gives additional priority to candidates with a CPRA of 98-100%, as shown in **Table 3**.

**Table 3: Priority for Highly Sensitized Candidates in Kidney Allocation<sup>33</sup>**

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%
<ul style="list-style-type: none"> <li>• <b>100% Highly Sensitized<sup>a</sup></b></li> <li>• Inside Circle Prior Living Donor<sup>a</sup></li> <li>• Inside Circle Pediatrics<sup>a</sup></li> <li>• Inside Circle Medically Urgent<sup>b</sup></li> <li>• <b>98%-99% Highly Sensitized</b></li> <li>• O-ABDRmm</li> <li>• Inside Circle Top 20%</li> <li>• EPTS</li> <li>• O-ABDRmm (All)</li> <li>• Inside Circle (All)</li> <li>• National Pediatrics</li> <li>• National (Top 20%)</li> <li>• National (All)</li> </ul>	<ul style="list-style-type: none"> <li>• <b>100% Highly Sensitized<sup>a</sup></b></li> <li>• Inside Circle Prior Living Donor<sup>a</sup></li> <li>• Inside Circle Pediatrics<sup>a</sup></li> <li>• Inside Circle Medically Urgent<sup>b</sup></li> <li>• <b>98%-99% Highly Sensitized</b></li> <li>• O-ABDRmm</li> <li>• Inside Circle Safety Net</li> <li>• Inside Circle (All)</li> <li>• National (All)</li> </ul>	<ul style="list-style-type: none"> <li>• <b>100% Highly Sensitized<sup>a</sup></b></li> <li>• Inside Circle Prior Living Donor<sup>a</sup></li> <li>• Inside Circle Medically Urgent<sup>b</sup></li> <li>• <b>98%-99% Highly Sensitized</b></li> <li>• O-ABDRmm</li> <li>• Inside Circle Safety Net</li> <li>• Inside Circle (All)</li> <li>• National (All)</li> <li>• Inside Circle (Dual)</li> <li>• National (Dual)</li> </ul>	<ul style="list-style-type: none"> <li>• <b>100% Highly Sensitized<sup>a</sup></b></li> <li>• Inside Circle Medically Urgent<sup>b</sup></li> <li>• <b>98%-99% Highly Sensitized</b></li> <li>• O-ABDRmm</li> <li>• Inside Circle Safety Net</li> <li>• Inside Circle (All)</li> <li>• Inside Circle (Dual)</li> <li>• National (All)</li> <li>• National (Dual)</li> </ul>

<sup>a</sup> Medically urgent sorted above non-medically urgent

<sup>b</sup> Medically urgent classification

Note: KDPI-Kidney donor profile index; O-ABDRmm-No mismatches for HLA A, 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.

As kidney allocation shifts toward continuous distribution, the classifications shown in **Table 3** will be eliminated and candidates will instead be prioritized for transplant via a composite allocation score. Once the Kidney and Pancreas Committees have refined the kidney and pancreas composite allocation scores, the MOT Committee could determine an appropriate composite allocation score threshold above which kidney-alone candidates should be offered kidneys ahead of multi-organ candidates. At this time, the Committee is interested in feedback on characteristics of candidates that should be prioritized, as this will inform how the Committee could determine a composite allocation score threshold in the future.

Despite the additional priority granted to highly sensitized candidates in current kidney allocation, these candidates may still have trouble finding a match for transplant, as indicated by slightly lower transplant

<sup>33</sup> "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](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).

rates for candidates with CPRA 98-100% relative to less sensitized candidates.<sup>34</sup> Furthermore, minority populations tend to have higher levels of sensitization, so these populations of kidney-alone candidates may be disproportionately impacted by multi-organ allocation.<sup>35</sup> Accordingly, the Committee supports requiring OPOs to offer kidneys to candidates with a CPRA of 98-100% ahead of multi-organ candidates, since the multi-organ candidates are more likely to get another suitable organ offer in a timely manner. The Committee holds that sensitized multi-organ candidates should also retain priority for transplant due to their reduced likelihood of receiving another suitable offer.

### *Medically Urgent Kidney Candidates*

The Committee agreed it would also be appropriate to prioritize offers for medically urgent kidney-alone candidates ahead of kidney multi-organ candidates, since the criteria to qualify for medically urgent status are strict, and the number of candidates who meet these criteria is small. Per *Policy 8.5.A.i Medically Urgent Status for Adult and Pediatric Candidates*, to qualify for medically urgent status, a candidate must be an active candidate accruing waiting time who has exhausted, or has a contraindication, to all dialysis access via all of the following methods:

- Vascular access in the upper left extremity
- Vascular access in the upper right extremity
- Vascular access in the lower left extremity
- Vascular access in the lower right extremity
- Peritoneal access in the abdomen

After exhaustion or contraindication to all dialysis via the methods listed above, the candidate must also either have exhausted dialysis, be currently dialyzed, or have a contraindication to dialysis via one of the following methods:

- Transhepatic IVC Catheter
- Translumbar IVC Catheter
- Other method of dialysis (must specify)

Between policy implementation on March 15, 2021, to August 1, 2022, only 29 candidates were listed with a medically urgent status.<sup>36</sup> Of these candidates, 14 were transplanted and 3 died. Given the small number of candidates, the Committee agreed it might be appropriate to require OPOs to offer kidneys to these candidates prior to offering kidneys to multi-organ kidney candidates.

### *Candidates Needing More Than Two Organs*

The OPTN does not currently have multi-organ policies specific to candidates who need more than two organs. The Committee suggested granting priority to candidates who need more than two organs since it can be hard to find a donor with multiple organs that are suitable for the same candidate. The Committee requests feedback on whether these candidates should receive priority ahead of other kidney multi-organ and kidney-alone candidates. Transplants involving a kidney and two or more other organs are rare, as shown in **Figure 8**, averaging about 10 such transplants per year from 2016-2021.

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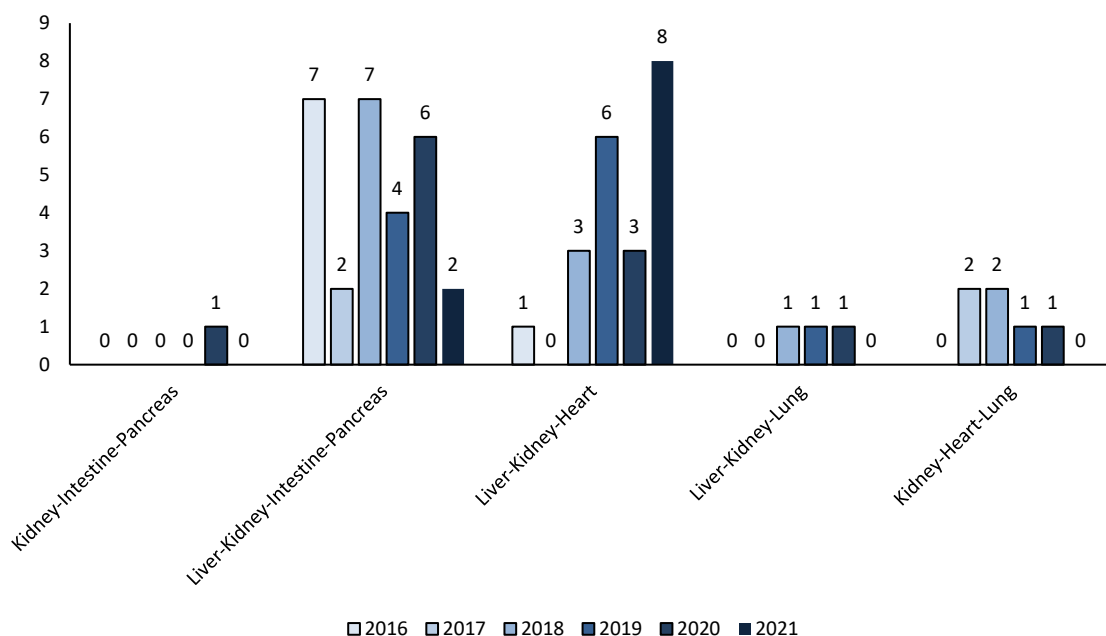
<sup>34</sup> "Eliminate Use of DSA and Region from Kidney Allocation One Year Post-Implementation Monitoring Report," OPTN, Descriptive Data Request, July 1, 2022, accessed November 4, 2022,

[https://optn.transplant.hrsa.gov/media/p20c3ada/data\\_report\\_kidney\\_full\\_20220624\\_1.pdf](https://optn.transplant.hrsa.gov/media/p20c3ada/data_report_kidney_full_20220624_1.pdf).

<sup>35</sup> Yoshio N. Hall, Andy I. Choi, Ping Xu, et al., "Racial Ethnic Differences in Rates and Determinants of Deceased Donor Kidney Transplantation," *Journal of the American Society of Nephrology* no. 22 (2011) 4(743-751), doi: 10.1681/ASN.2010080819.

<sup>36</sup> OPTN data as of August 1, 2022.

**Figure 8: Multi-Organ Transplants Involving Kidneys and Two or More Other Organs, 2016 - 2021<sup>37</sup>**



### *Kidney-Pancreas and Pediatric Kidney Candidates*

As shown in **Table 4** below, pediatric candidates receive priority for low KDPI kidneys in current kidney allocation. However, per *Policy 11.5.A Kidney-Pancreas Allocation Order*, if a host OPO has both a kidney and a pancreas to offer for allocation, then the OPO must first offer the kidney and pancreas to kidney-pancreas candidates within 250 nm. Accordingly, kidney-pancreas candidates often also receive low KDPI kidneys, as shown in **Figure 4** above. The Pediatric Committee provided feedback that kidney-pancreas candidates that are not medically urgent should not get priority over pediatric kidney candidates. However, since medical urgency has not been defined for pancreas or kidney-pancreas, the OPTN has not yet updated allocation policy to better stratify organ offers to medically urgent kidney-pancreas candidates ahead of candidates who do not have medical urgency. The Committee also noted that comparing mortality rates between kidney-pancreas and pediatric kidney candidates would not capture the impact of delaying transplant on the physical and cognitive growth of pediatric candidates.<sup>38</sup>

The Committee agreed that it may be appropriate to prioritize some pediatric kidney candidates ahead of kidney-pancreas and/or other kidney multi-organ candidates, particularly if they have over one year of waiting time or failed peritoneal dialysis. If there is a need to further stratify pediatric candidates, the Committee could consider introducing a glomerular filtration rate (GFR) threshold for priority shares. The Committee could also consider whether there is justification for prioritizing candidates by age more continuously. Clinically, a 17-year-old candidate may not be very different from a 19-year-old candidate, but based on federal law, the 17-year-old candidate is considered pediatric and the 19-year-old candidate is not.<sup>39</sup>

<sup>37</sup> OPTN data as of November 4, 2022. There were no liver-kidney-pancreas, liver-kidney-intestine, or kidney-pancreas-heart transplants performed from 2016-2021.

<sup>38</sup> Phil Icard, Stephen R. Hooper, Debbie S. Gipson, et al., "Cognitive improvement in children with CKD after transplant," *Pediatric Transplantation* 14 (2010): 887-890, <https://doi.org/10.1111/j.1399-3046.2010.01359.x>.

<sup>39</sup> 42 USC §274(b)(2)(O).



**Table 4: Priority for Pediatric Candidates in Kidney Allocation<sup>40</sup>**

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%
<ul style="list-style-type: none"> <li>• 100% Highly Sensitized</li> <li>• Inside Circle Prior Living Donor<sup>a</sup></li> <li>• <b>Inside Circle Pediatrics</b></li> <li>• Inside Circle Medically Urgent<sup>b</sup></li> <li>• 98%-99% Highly Sensitized</li> <li>• 0-ABDRmm</li> <li>• Inside Circle Top 20%</li> <li>• EPTS</li> <li>• 0-ABDRmm (All)</li> <li>• Inside Circle (All)</li> <li>• <b>National Pediatrics</b></li> <li>• National (Top 20%)</li> <li>• National (All)</li> </ul>	<ul style="list-style-type: none"> <li>• 100% Highly Sensitized</li> <li>• Inside Circle Prior Living Donor<sup>a</sup></li> <li>• <b>Inside Circle Pediatrics</b></li> <li>• Inside Circle Medically Urgent<sup>b</sup></li> <li>• 98%-99% Highly Sensitized</li> <li>• 0-ABDRmm</li> <li>• Inside Circle Safety Net</li> <li>• Inside Circle (All)</li> <li>• National (All)</li> </ul>	<ul style="list-style-type: none"> <li>• 100% Highly Sensitized</li> <li>• Inside Circle Prior Living Donor<sup>a</sup></li> <li>• Inside Circle Medically Urgent</li> <li>• 98%-99% Highly Sensitized</li> <li>• 0-ABDRmm</li> <li>• Inside Circle Safety Net</li> <li>• Inside Circle (All)</li> <li>• National (All)</li> <li>• Inside Circle (Dual)</li> <li>• National (Dual)</li> </ul>	<ul style="list-style-type: none"> <li>• 100% Highly Sensitized</li> <li>• Inside Circle Medically Urgent</li> <li>• 98%-99% Highly Sensitized</li> <li>• 0-ABDRmm</li> <li>• Inside Circle Safety Net</li> <li>• Inside Circle (All)</li> <li>• Inside Circle (Dual)</li> <li>• National (All)</li> <li>• National (Dual)</li> </ul>

## Limit Kidney Multi-Organ Allocation

Aside from requiring shares to kidney-alone candidates ahead of multi-organ candidates, there are other ways to place additional limits on kidney multi-organ allocation. First, the Committee supports the increased use of safety net and sequential transplant, particularly once the safety nets for kidney-after-heart and kidney-after-lung transplant are implemented in 2023.<sup>41</sup> A safety net gives recipients of a single-organ transplant some priority to receive a kidney for a period of time following the single-organ transplant, if the recipients meet criteria for kidney dysfunction. Currently, a safety net is in place for kidney-after-liver transplantation (see *Policy 8.5.G Prioritization for Liver Recipients on the Kidney Waiting List*).

Second, the Committee suggested considering post-transplant outcomes in determining which candidate gets priority, given that multi-organ recipients tend to have worse outcomes. Currently, estimated post-transplant survival is incorporated into lung allocation<sup>42</sup> but similar scores have not been incorporated for liver, heart, or pancreas, so this is a potential area of future analysis and policy development for other organs.

Third, the Committee could explore restricting the types of kidneys offered to multi-organ candidates. For example, Sequence B kidneys (those with a KDPI of 21-34%, as shown in **Table 4**) could be excluded from required shares to multi-organ candidates to free up more of those kidneys for kidney-alone candidates. Currently, there are no restrictions on the KDPI of kidneys offered to multi-organ candidates for simultaneous transplant. However, of the kidneys with a KDPI less than 20% that go to recipients

<sup>40</sup> "Addressing Medically Urgent Candidates in the New Kidney Allocation System," OPTN, accessed December 20, 2022, [https://optn.transplant.hrsa.gov/learn/professional-education/kidney-allocation-system/addressing-medically-urgent-candidates-in-the-new-kidney-allocation-system/#TK\\_FAQ](https://optn.transplant.hrsa.gov/learn/professional-education/kidney-allocation-system/addressing-medically-urgent-candidates-in-the-new-kidney-allocation-system/#TK_FAQ).

<sup>41</sup> "Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation," OPTN, Policy Notice, accessed November 4, 2022, [https://optn.transplant.hrsa.gov/media/erucde2m/policy-notice\\_est-elgblty-crit-and-safety-for-hrt-kid-and-lung-kid-alloc\\_mot.pdf](https://optn.transplant.hrsa.gov/media/erucde2m/policy-notice_est-elgblty-crit-and-safety-for-hrt-kid-and-lung-kid-alloc_mot.pdf).

<sup>42</sup> "Establish Continuous Distribution of Lungs," OPTN, Policy Notice, accessed December 20, 2022, [https://optn.transplant.hrsa.gov/media/eyvd01ia/policy-notice\\_lung-cd-update\\_lung.pdf](https://optn.transplant.hrsa.gov/media/eyvd01ia/policy-notice_lung-cd-update_lung.pdf).

with an estimated post-transplant survival (EPTS) score greater than 20%, 66% of those kidneys were used in multi-organ transplants.<sup>43</sup> Those kidneys would otherwise have been prioritized for pediatric kidney candidates and other kidney candidates with longer expected post-transplant survival.

Finally, the Committee could propose requiring that if one kidney is offered to a multi-organ candidate, then the other kidney must be offered to a kidney-alone candidate. A similar approach is used in Canada, in which one kidney is allocated locally and the second kidney is allocated by a national or provincial list, which includes multi-organ candidates, kidney-pancreas candidates, pancreas-alone candidates, and pediatric candidates.<sup>44</sup> Alternatively, the Committee could propose that one of the two kidneys must be offered to a “required share” kidney-alone candidate first (e.g. one who is highly sensitized, medically urgent, or a pediatric candidate), and if it is not accepted by one of those candidates, then the second kidney could also be offered to a kidney multi-organ candidate prior to being offered to other kidney-alone candidates.

## Offering Kidneys to Candidates of Equal Priority

OPTN policy specifies when an OPO must offer a kidney along with a heart, liver, lung, or pancreas, but does not provide any direction to OPOs on how to allocate the kidney among these required shares. In other words, required shares for heart-kidney, liver-kidney, lung-kidney, and pancreas-kidney all carry equal weight in policy. If several kidney multi-organ candidates appear across different match runs as qualifying for required shares, the OPO must decide how to allocate the kidneys among these different candidates. The Committee notes that comparing priority for transplant among these different populations is challenging. For example, medical urgency is estimated differently for heart, liver, and lung, and pancreas allocation does not account for medical urgency. Additionally, organ-specific medical urgency scores may not account for the disease pathology of candidates experiencing failure in multiple organs. The Committee requests feedback on whether it is appropriate for policy to dictate an allocation order to OPOs across these various candidate populations, and if so, what data should be used to inform such an allocation order. The Committee also requests feedback on whether policy should dictate when to offer the left kidney versus the right kidney.

## Organ Offer Acceptance and Required Shares

Organ offer acceptance is defined in OPTN policy as “when the transplant hospital notifies the host OPO that it accepts the organ offer for an intended recipient, pending review of organ anatomy. For kidney, acceptance is also pending final crossmatch.” In August 2022, the OPTN Operations and Safety Committee proposed updated definitions for primary offer acceptance and back-up acceptance to align with their proposed tiered framework for improving the efficiency of organ offers.<sup>45</sup> These definitions have not been approved, but the definition of organ offer acceptance may be updated by a future proposal.

*Policy 5.6.D Effect of Acceptance* states that “when a transplant hospital accepts an OPO’s organ offer without conditions, this acceptance binds the transplant hospital and OPO unless they mutually agree on an alternative allocation of the organ.” OPO members have provided public comment feedback on multi-organ policy proposals stating concerns that policies requiring multi-organ shares may conflict

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<sup>43</sup> S. Ali Husain et al., “Regional Disparities in Transplantation,” 357.

<sup>44</sup> “Policies: Wait list, organ offers and allocation,” Trillium Gift of Life Network, May 25, 2022, accessed November 4, 2022, <https://www.giftoflife.on.ca/resources/pdf/healthcare/TP-9-100.pdf>.

<sup>45</sup> “Redefining Provisional Yes and the Approach to Organ Offers,” OPTN, Concept Paper, August 2022, accessed November 4, 2022, [https://optn.transplant.hrsa.gov/media/pvxlsl0p/redfng-prov-ves-and-apprch-to-org-offers\\_osc\\_pc-summer-2022.pdf](https://optn.transplant.hrsa.gov/media/pvxlsl0p/redfng-prov-ves-and-apprch-to-org-offers_osc_pc-summer-2022.pdf).

with this policy regarding the binding nature of organ offer acceptance.<sup>46</sup> OPO members are particularly concerned about running into this situation in the event of a late turndown. For example, an OPO may have acceptances for a heart and two kidneys, and then have a late turndown for the heart. If the next candidate on the heart match run qualifies for a required heart-kidney share, the OPO no longer has the kidney to offer along with the heart due to the binding acceptances for both kidneys. The Committee requests feedback on how to clarify in policy that binding organ offer acceptance takes priority over required multi-organ shares. The various kidney multi-organ policies use different language to describe the OPO’s obligation under the policy, as summarized in **Table 5**.

**Table 5. Policy Language Describing Required Kidney Multi-Organ Offers**

Organ combination	Policy language related to required offers
Liver-kidney <sup>47</sup>	If a host OPO is offering a kidney and a liver from the same deceased donor, then before allocating the kidney to kidney alone candidates, the host OPO must offer the kidney with the liver...
Heart-kidney	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...
Lung-kidney	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...
Pancreas-kidney	If a host OPO has both a kidney and a pancreas to offer for allocation, then the host OPO must offer the kidney and the pancreas...

## Balancing Direction vs. Flexibility

OPO members have requested more direction on managing multi-organ allocation. Increasing the clarity of multi-organ policies may improve the efficiency of multi-organ allocation by reducing confusion, avoiding the need to escalate decisions to senior OPO staff, and reducing conflict with transplant programs. On the other hand, OPOs are managing a series of complicated logistics while placing multiple organs from one donor, and late turndowns, travel delays, and other challenges can lead to unusual situations that may not be accounted for in policy. Furthermore, providing too much direction in policy by stipulating a strict match run order may impede allocation, as generally OPOs are offering organs off of several match runs at once. Accordingly, the Committee requests feedback on how to structure policy in a way that will provide the necessary level of direction for multi-organ allocation without impinging upon the ability of OPOs to place organs efficiently.

## NOTA and Final Rule Analysis

The Committee submits this concept paper project under the authority of the National Organ Transplant Act (NOTA) to “establish membership criteria and medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria,”<sup>48</sup> and the OPTN Final Rule, which states, “the OPTN Board of Directors shall be responsible for developing... policies for the

<sup>46</sup> “Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation,” OPTN.

<sup>47</sup> The Committee has a policy proposal out for public comment this cycle which would align this policy language for liver-kidney allocation with the language shown in Table 5 for heart-kidney and lung-kidney allocation. See <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/expand-required-simultaneous-liver-kidney-allocation/>.

<sup>48</sup> 42 USC §274(b)(2)(B).

equitable allocation of cadaveric organs"<sup>49,50</sup> which "shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate."<sup>51</sup> Feedback provided on this concept paper will be used to develop a policy proposal that creates new rules for organ procurement organizations on offering organs from multi-organ donors to kidney-alone and kidney multi-organ candidates, including kidney-pancreas, heart-kidney, lung-kidney, and liver-kidney candidates.

## Conclusion

The Committee aims to establish an updated framework for kidney multi-organ allocation to improve equity and efficiency in multi-organ allocation. The Committee requests community feedback on how to best achieve this goal to inform a future policy proposal.

## Considerations for the Community

The Committee requests feedback on all aspects of this concept paper, including the following questions:

- How do patients recommend improving equity in access to transplant between kidney-alone and kidney multi-organ candidates?
- How do transplant professionals recommend improving equity in access to transplant between kidney-alone and kidney multi-organ candidates?
- Should OPOs be required to offer kidneys to some kidney-alone candidates prior to offering kidneys to multi-organ candidates?
  - If yes – what characteristics should prioritize kidney-alone candidates for offers prior to multi-organ candidates?
  - Should prior living donors receive offers prior to kidney multi-organ candidates?
- Should some or all pediatric kidney-alone candidates get additional priority for low KDPI kidneys relative to kidney multi-organ candidates?
- In the absence of policy relating to kidney laterality, how do OPOs currently decide when to offer the left vs. right kidney?
- Should the OPTN develop policy on when to offer the left vs. right kidney?
- Is it appropriate for policy to distinguish an organ offer order between liver-kidney, heart-kidney, lung-kidney, and pancreas-kidney candidates?
  - If so, what data should be used to inform such an allocation order?
- How can the OPTN provide the necessary level of direction for multi-organ allocation without impinging upon the ability of OPOs to place organs efficiently?
- Are there other challenges related to multi-organ allocation not outlined in this concept paper that the Committee should address?

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<sup>49</sup> 42 CFR 121.4(a)(1).

<sup>50</sup> 42 CFR 121.8(a).

<sup>51</sup> 42 CFR 121.8(a)(4).