OPTN

Briefing to the OPTN Board of Directors on

Identify Priority Shares in Kidney Multi-Organ Allocation

OPTN Ad Hoc Multi-Organ Transplantation Committee

Prepared by: Alex Carmack
UNOS Policy and Community Relations Department

Contents

Identify Priority Shares in Kidney Multi-Organ Allocation

Sponsoring Committee: *Ad Hoc Multi-Organ Transplantation*
Public Comment Period: *January 19, 2023 – March 18, 2023*
Board of Directors Date: *June 26, 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 the concept paper was to introduce ideas and request feedback from the community to inform a future policy proposal. The majority of the feedback received from the community focused on ensuring specific groups maintaining their priority over multi-organ transplant, MOT, candidates. These specific groups include pediatric candidates, high Calculate Panel-Reactive Antibody (CPRA) candidates, medically urgent kidney-alone candidates, and prior living donors. The community also provided feedback regarding the MOT status of kidney with pancreas candidates, and the need for better guidance for organ procurement organizations, OPOs, during MOT allocation. Finally, the concept of designating one kidney for MOT and the other for kidney-alone transplantation from the same donor garnered support from a large portion of the community.

Overview of the Request for Feedback

Purpose

The purpose of this concept paper was to solicit feedback on allocating kidneys between single-organ and multi-organ candidates to improve equity and efficiency. 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 it can be harder for candidates to find a good match with two or more organs from the same donor,[1] and 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.[2] 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. The OPTN Ethics Committee highlighted these equity concerns in a 2019 white paper, noting that inconsistency in MOT allocation could result in lower utility of organ allocation, and disadvantage medically urgent patients.[3] This concept paper was a continuation of the Ethics Committee's white paper, in that it was a step in standardizing organ allocation for MOT kidney combination and sought community input for priority shares in kidney.

[1] 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. 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.

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

[3] "Ethical Implications of Multi-Organ Transplants," Public Comment Proposal. OPTN Ethics Committee. January 22, 2019-March 22, 2019. https://optn.transplant.hrsa.gov/media/2801/ethics_publiccomment_20190122.pdf

Questions asked of the Community

- 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 Kidney Donor Profile Index (KDPI) kidneys relative to kidney multi-organ candidates?
- Should further evaluation of left vs right kidney be explored for MOT allocation, what are the best practices for determining kidney laterality during allocation?
- 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?

Summary of Public Comment Feedback

In total, the concept paper received 106 total comments, and was a discussion agenda item at all OPTN regional meetings. In addition to the OPTN regional meetings, the concept paper was presented to the following OPTN committees the Kidney Transplantation, Pediatric, Transplant Coordinators, Operations and Safety, Liver and Intestine, Transplant Administrators, Organ Procurement Organizations, Histocompatibility, Pancreas Transplantation, and the Executive Committee. The following groups emerged as needing priority considerations over MOT candidates listed in order of frequency mentioned:

1. Pediatric candidates
2. High CPRA candidates
3. Medically urgent kidney-alone candidates
4. Prior living donors

In addition to these groups the concepts were also frequently mentioned by the community:

1. designating kidney with pancreas candidates as MOT
2. Guidance for and prioritization of MOT for OPOs
3. Designating a one kidney for MOT and the other for kidney-alone candidates from the same donor

This concept paper was present to **Figure 1** shows the amount of participation by member type. The largest participating member groups were transplant hospitals at OPTN regional meetings.

Figure 1. Participation by Member Types

OPTN Member Type	Number of Comments Received
Transplant hospital	50
Organ procurement organization	12
Histocompatibility lab	8
Member type not provided	22
Candidate, recipient, living donor, candidate family, recipient family, donor family	6
Stakeholder organization	7
Non-OPTN member	1
Total	**106**

Pediatrics

Pediatric candidates were mentioned more than any other group for receiving priority in kidney allocation above adult multi-organ transplant (MOT) candidates, in large part because of the unique anatomy specifications of pediatric candidates and the ethical implications for pediatric transplantation. At every regional meeting, except one, participants supported prioritizing pediatric candidates above adult MOT candidates. Some within the community are in favor of prioritizing all pediatric candidates rather than certain pediatric groups. Members of the community also voiced their concern, and frustration, regarding the use of low KDPI kidneys being used in adult MOT rather than pediatric kidney-alone or pediatric MOT. Additionally, some in the community suggested prioritizing pediatric multi-organ candidates over pediatric kidney-alone and most adult multi-organ and kidney-alone candidates.

> "A member noted that from a pediatric standpoint, seeing 1-20% KDPI kidneys going to MOT candidates is difficult because pediatric candidates face the potential for additional kidney transplants if they don't receive the best possible kidney. [The member] added that laterality is also an issue for pediatrics because anatomy, whether it is a vessel or size issue, can impact organ offer acceptance." OPTN Transplant Coordinators Committee, public comment submission.[4]

High Calculated Panel-Reactive Antibody (CPRA)

Highly sensitized candidates, often defined as candidates with a CPRA of 98% or higher, were another frequently mentioned category of candidates for prioritization. This extremely difficult to match candidate group was mentioned as needing prioritization at every regional meeting, by the majority of

[4] OPTN Transplant Coordinators Committee, "Identify Priority Shares in Kidney Multi-Organ Allocation" public comment submission. March 14, 2023. https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/identify-priority-shares-in-kidney-multi-organ-allocation/

OPTN committees who reviewed the concept paper, and the majority of organizations who participated in public comment. Most comments were clear that high CPRA kidney-alone candidates should be prioritized over most multi-organ candidates.

> "Candidates with a CPRA of >98% need to be prioritized within multi-organ allocation, and CPRA >98% single organ kidney candidates need to be prioritized over less sensitized MOT candidates," OPTN Histocompatibility Committee public comment submission.[5]

Medically Urgent Kidney-Alone

Medically urgent kidney-alone candidates were a frequently mentioned group that should receive priority over non-medically urgent multi-organ candidates. Similar to pediatrics and high CPRA candidates, medically urgent kidney-alone candidates were mentioned at every regional meeting. Commenters often placed these three groups in the same prioritization category.

Prior Living Donor

Prior living donors were also mentioned as deserving of some level of priority. Commenters pointed out the selflessness of living donors should be repaid in their time of need. Several acknowledged that not providing living donors with priority could disincentivize others from becoming living donors. Prior living donors who donated within the United States currently receive some priority in kidney-alone allocation, and under new continuous distribution frameworks. In current kidney policy, a prior living donor receives four points towards their allocation score.[6] Under the recently implemented lung continuous distribution framework, prior living donors receive an additional five points within the Patient Access attribute.[7] This is a score reserved exclusively for prior living donors only, and a criterion that did not exist in the prior lung allocation framework. The Kidney, Pancreas, Liver-Intestine, and Heart Transplantation Committees have all discussed including a similar attribute for living donors as they transition to continuous distribution.

Kidney and Pancreas

Multiple comments were made regarding the classification of kidney-pancreas as a multi-organ transplant combination that must be prioritized among other multi-organ combinations. Nearly every pancreas transplant is accompanied with a simultaneous kidney transplant; both patients and professionals pointed out that forcing these candidates to compete for kidneys designated for other multi-organ combinations puts pancreas candidates at a disadvantage.

Guidance and MOT Prioritization Allocation

The community consistently requested clear guidance regarding multi-organ allocation for organ procurement organizations. This concern was shared by partner organizations, OPTN committees, and at

[5] OPTN Histocompatibility Committee, "identify Priority Shares in Kidney Multi-Organ Allocation" public comment submission. March 14, 2023. https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/identify-priority-shares-in-kidney-multi-organ-allocation/
[6] *OPTN Policy* 8.2; Table 8-1.; *OPTN Policy* 8.4.E
[7] *OPTN Policy* 10.1.D.2

regional meetings. Commenters stated the need for clarity around multi-organ allocation would assist in decreasing the time between allocation and transplant. One commenter did suggest providing some latitude for OPOs to allocate organs for MOT.

> "Support for the idea of balancing single kidney candidates with MOT candidates by including certain criteria or restrictions. Consistency across all OPOs is necessary when it comes to allocating the kidneys to kidney alone versus MOT," OPTN Transplant Administrators Committee public comment submission.[8]

> "Additionally, we welcome policy guidance on prioritization among candidates for organ offers for liver-kidney, heart-kidney, lung-kidney, and pancreas-kidney candidates," Association of Organ Procurement Organizations public comment submission.[9]

Multiple Kidney Recipients from a Single Donor Allocation

Multiple members of the community also offered as a solution duplicate donor kidney allocation, where a single donor has one kidney designated for kidney-alone candidate and the other kidney from the same donor goes to a MOT candidate, as a possible solution for pediatric prioritization. This sentiment was shared by multiple stakeholder organizations, community members, OPTN committees, and at multiple regional meetings.

Next Steps

The Ad Hoc Multi-Organ Transplantation Committee will use this feedback to begin developing policies addressing the concerns of the community around multi-organ and kidney-alone allocation policies. It is clear from public comment that there is broad community support for prioritizing pediatric candidates, candidates with a high CPRA, and medically urgent candidates above MOT candidates that do not fit into these categories. The Committee will explore ways to provide clarity for OPOs in allocation policy. This could include ways to prioritize certain kidney-alone candidates over certain multi-organ candidates, creating a prioritization framework that addresses different MOT combinations within kidney allocation. Additionally, as part of the Committee's effort to address better guidance within MOT allocation the Committee will examine OPTN *Policy 5.6.D Effect of Acceptance*, which is known to create confusion for OPOs during MOT allocation. The committee will also research the viability of allocating one donor kidney to an MOT candidate, and the second kidney from the same donor to a kidney-alone candidate. Finally, the Committee will consider examining the possibility of reclassifying simultaneous pancreas-kidney candidates separately from other MOT candidates.

[8] OPTN Transplant Administrators Committee, "Identify Priority Shares in Kidney Multi-Organ Allocation" public comment submission. March 14, 2023. https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/identify-priority-shares-in-kidney-multi-organ-allocation/

[9] Association of Organ Procurement Organizations, "Identify Priority Shares in Kidney Multi-Organ Allocation" public comment submission. March 14, 2023. https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/identify-priority-shares-in-kidney-multi-organ-allocation/