OPTN

Public Comment Proposal

Modify Effect of Acceptance Policy

OPTN Ad Hoc Multi-Organ Transplantation Committee

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Modify Effect of Acceptance Policy

Affected Policies: *5.6.D Effect of Acceptance*
Sponsoring Committee: *Ad Hoc Multi-Organ Transplantation*
Public Comment Period: *January 23, 2024 – March 19, 2024*

Executive Summary

During the Winter 2023 OPTN public comment period, the Ad Hoc Multi-Organ Transplantation Committee (Committee) requested feedback on the concept paper *Identify Priority Shares in Kidney-Multi-Organ Allocation*.[1] The concept paper was the first step in a project that aims 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. One of the topics included in the concept paper was how to handle situations in which organ offer acceptance conflicts with a multi-organ offer required by policy. OPO members provided public comment feedback stating concerns that policies requiring multi-organ shares may conflict with the requirements in *Policy 5.6.D: Effect of Acceptance*. The purpose of this proposal is to clarify that organ offer acceptance takes priority over requirements to offer more than one organ to a single candidate if the second organ has already been accepted by a transplant program.

It is important to note that OPOs are still required to place multi-organ combinations according to current OPTN policies. Various multi-organ policies require the host OPO to allocate to multi-organ candidates that meet a certain criterion before offering to kidney-alone candidates. This proposal addresses the scenario where organs have been accepted and there is a subsequent organ offer refusal. If a multi-organ candidate is the next candidate on the match run and the second required organ has already been accepted by a transplant program, the OPO is not required to offer both organs to that candidate.

The Committee is requesting public comment feedback, including input on the following questions:

- Should a specific timeframe be included in the policy language? For example, if an organ has been accepted by a transplant program and the donor recovery has been scheduled.
- Should this apply only after all organs are allocated and accepted, including required multi-organ shares?
- Do patients and donor families support the concept that accepted organs take priority over required multi-organ shares?

The Committee also has a Request for Feedback (RFF) currently out for public comment. This RFF is requesting community input on how to identify concepts for modifying multi-organ policies.

[1] "Identify Priority Shares in Kidney Multi-Organ Allocation," OPTN, Concept Paper, accessed October 19, 2023, available https://optn.transplant.hrsa.gov/media/mc0hfxrg/priority-shares-in-kidney-mot_concept_pc-winter-2023.pdf.

Purpose

The purpose of this proposal is to clarify that organ offer acceptance takes priority over requirements to offer more than one organ to a single candidate if the second organ has already been accepted by a transplant program.

Background

From January – March 2023, the Ad Hoc Multi-Organ Transplantation Committee (Committee) requested feedback on the concept paper *Identify Priority Shares in Kidney-Multi-Organ Allocation*.[2] One of the topics included in the concept paper was how to handle situations in which organ offer acceptance conflicts with a multi-organ offer required by policy. Organ offer acceptance is defined in OPTN *Policy 1.2: Definitions* 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." OPTN *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."

Public comment feedback supported clarifying that required multi-organ offers do not supersede an offer acceptance. The Association of Organ Procurement Organizations said, "We look forward to having a framework that includes better guidance for how to resolve issues where required shares conflict, such as when a previously accepted organ is declined and offered to the next listed recipient requiring a multi-organ transplant that includes an organ already allocated to another recipient… A blueprint that guides organ allocation should lead to increases in national consistency in how organs are allocated from multi-organ donors but should not be so prescriptive as to penalize members when flexibility is needed to achieve a transplant outcome, such as when late organ declines occur." The American Society of Pediatric Nephrology said, "The Society also strongly supports clarifying existing policy to state that a kidney, once accepted by a kidney-alone candidate, cannot be reallocated to a multi-organ required share. This type of reallocation is a violation of long-standing OPTN policy, places undue burden on patients and families who travel to the transplant hospital only to have their hopes dashed, and creates confusion and mistrust in the system."

Following the public comment period, the Committee requested and reviewed additional data regarding kidney multi-organ allocation to assess how to give more direction to OPOs to improve the efficiency of multi-organ allocation while also considering how to provide more equity in access to transplant between kidney-alone and kidney multi-organ candidates. The Committee's discussions are outlined in more detail in the Concepts for Modifying Multi-Organ Policies Request for Feedback currently out for public comment. While continuing to assess approaches for improving multi-organ allocation, the Committee agreed to propose policy changes to clarify expectations for OPOs on how to comply with multi-organ allocation policies when a second organ is no longer available for a required share.

Overview of Proposal

The Committee proposes clarifying that organ offer acceptance takes priority over requirements to offer more than one organ to a single candidate. When an organ has been accepted by a transplant program, that offer is binding according to *Policy 5.6.D: Effect of Acceptance* and that organ is no longer available for subsequent offers. With the recent focus on increasing efficiency in organ placement, this allows

[2] "Identify Priority Shares in Kidney Multi-Organ Allocation," OPTN, Concept Paper, accessed October 19, 2023, available https://optn.transplant.hrsa.gov/media/mc0hfxrg/priority-shares-in-kidney-mot_concept_pc-winter-2023.pdf.

OPOs to move forward with placing single organs without holding back offers in case there is a late organ offer refusal of a previously accepted organ and multi-organ candidates are on the match run.

It is important to note that OPOs are still required to place multi-organ combinations according to current OPTN policies. For example, *Policy 5.10: Allocation of Multi-Organ Combinations* establishes requirements for placing heart-kidney, lung-kidney, heart-liver, and lung liver combinations. *Policy 5.10.E: Allocation of Heart-Kidneys* specifically states that "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 the eligibility criteria." Additionally, both *Policy 11.4.A: Kidney-Pancreas Allocation Order* and *Policy 9.9: Liver-Kidney Allocation* have requirements for when to offer to these combinations prior to offering to kidney alone candidates.

Current policy does not address which combinations take priority and remains at the discretion of the OPOs. The issue of MOT prioritization will be the top priority for the Committee to address in 2024. The community is encouraged to comment on the *Request for Feedback: Concepts for Modifying Multi-Organ Policies* currently out for public comment. Feedback received will help inform future multi-organ policies, including MOT prioritization.

Table 1 shows how the number of multi-organ transplants have increased over the past 10 years.

Table 1: Multi-Organ Transplants (All Combinations)[3]

2022	2021	2020	2019	2018	2017	2016	2015	2014	2013
1,340	1,257	1,200	1,074	1,016	1,035	985	892	774	674

With the increase in multi-organ transplants, it is imperative that policies be developed to allow OPOs to efficiently place organs. Previous public comments on multi-organ policy proposals stated concerns that policies requiring multi-organ shares may conflict with this policy regarding the binding nature of organ offer acceptance.[4] OPO members are particularly concerned about running into this situation in the event of a late turndown. 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 match 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.

It is possible that this proposal may result in fewer multi-organ transplants since OPOs would proceed with making primary offers for single organs like a kidney once other organs like the heart and lungs have been accepted. However, since kidney multi-organ candidates tend to receive organ offers before kidney-alone candidates,[5] the Committee does not anticipate that this proposal would have a substantial impact on access to transplant for multi-organ candidates.

NOTA and Final Rule Analysis

The Committee submits this proposal for consideration under the authority of the National Organ Transplant Act of 1984 (NOTA) and the OPTN Final Rule. NOTA requires the OPTN to "establish…medical criteria for allocating organs and provide to members of the public an opportunity to comment with

[3] https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/.
[4] "Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation," OPTN.
[5] 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* 21 no. 6 (2021): 2161-2174, https://doi.org/10.1111/ajt.16390.

respect to such criteria."[6] The OPTN Final Rule states the OPTN "shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[7] This proposal would clarify the effect of acceptance and how it applies to the allocation of organs with multi-organ candidates and single organ candidates.

The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed "in accordance with §121.8," which 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."[8] This proposal:

- **Is based on sound medical judgment**[9] to balance the need to place organs and avoid delays while prioritizing allocation of organs for multi-organ candidates and single organ candidates. This also allows transplant programs to proceed with coordinating transplants for organs accepted for candidates without concern that a previously accepted organ may be reallocated.
- **Is designed to avoid wasting organs**[10] **by** decreasing the number of organs recovered but not transplanted which maximizes the gift of organ donation by using each donated organ to its full potential. This proposal allows OPOs to move forward with allocation more expediently and reduce the cold ischemic time on organs, which may help prevent non-use of organs.
- **Is designed to…promote patient access to transplantation**[11] **by** giving similarly situated candidates equitable opportunities to receive an organ offer. This proposal allows organ placement with single organ candidates that may otherwise be placed with multi-organ candidates.
- **Promotes the efficient management of organ placement**[12] **by** taking into account the costs and logistics of procuring and transplanting organs. This proposal allows OPOs to move forward with placing all organs without holding organs in case of an organ offer refusal to streamline the logistics of coordinating organ recovery and transplantation.
- **Is not based on the candidate's place of residence or place of listing.**[13]

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient.[14] The proposal is not specific to an organ type[15] because it is intended to provide more direction to OPOs on how to manage allocation of multiple organs across several different match runs.

Although the proposal outlined in this briefing paper addresses certain aspects of the Final Rule listed above, the Committee does not expect impacts on the following aspects of the Final Rule:

[6] 42 USC §274(b)(2)(B).
[7] 42 CFR §121.4(a)(1).
[8] 42 CFR §121.8(a).
[9] 42 CFR §121.8(a)(1).
[10] 42 CFR §121.8(a)(5).
[11] Id.
[12] Id.
[13] 42 CFR §121.8(a)(8).
[14] 42 CFR §121.8(a)(3).
[15] 42 CFR §121.8(a)(4).

- **Seeks to achieve the best use of donated organs[16] by** ensuring organs are allocated and transplanted according to medical urgency. This proposal does not change how candidates are ranked on each organ match run and therefore preserves the considerations for medical urgency that are incorporated into the organ-specific allocation policies.
- **Is designed to avoid futile transplants[17]:** This proposal should not result in transplanting patients that are unlikely to have good post-transplant outcomes as it does not impact patient selection for transplant.

Transition Plan

The Final Rule also requires the OPTN to "consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies" whenever organ allocation policies are revised.[18] The Committee did not identify any populations that 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, as this proposal is intended to clarify existing obligations under policy that organ offer acceptance "binds the transplant hospital and OPO unless they mutually agree on an alternative allocation of the organ."

Implementation Considerations

Member and OPTN Operations

Operations affecting Organ Procurement Organizations

OPOs may need to evaluate their internal policies and procedures to account for this policy change.

Operations affecting Transplant Hospitals

Transplant hospitals may need to evaluate their internal policies and procedures to account for this policy change.

Operations affecting Histocompatibility Laboratories

There is no anticipated impact on histocompatibility laboratories.

Operations affecting the OPTN

There is no anticipated impact on OPTN operations.

Potential Impact on Select Patient Populations

There is the potential for fewer offers for MOT candidates if OPOs no longer hold back on final placement of a second organ in case of a late turndown. However, this change may improve access to single organs and improve efficiency in placement of other organs.

[16] 42 CFR §121.8(a)(2).
[17] Id.
[18] 42 CFR § 121.8(d).

Projected Fiscal Impact

Projected Impact on Organ Procurement Organizations

There is no projected fiscal impact on organ procurement organizations.

Projected Impact on Transplant Hospitals

There is no projected fiscal impact on transplant hospitals.

Projected Impact on Histocompatibility Laboratories

There is no projected fiscal impact on histocompatibility laboratories.

Projected Impact on the OPTN

The OPTN contractor estimates that 190 hours would be needed to implement this proposal. Implementation would involve updates and education to OPOs and transplant hospitals. These entities may need to evaluate and adjust their internal policies and procedures to comply with the proposed policy changes. The OPTN contractor estimates 15 hours would be needed for ongoing support. Ongoing support will include answering member questions, as necessary.

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."

The OPTN will continue to review all deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to OPTN policy, and staff will investigate potential policy violations that are identified.

Policy Evaluation

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

This policy will monitor MOT, kidney, pancreas, liver, heart, and lung alone as data permits and after a sufficient sample size has accumulated. Metrics include:

- Number of MOT transplants and single organ transplants
    - MOT transplants will be stratified by organ combinations
- Waiting list deaths for MOT candidates and single organ candidates
    - Counts will be stratified by medical urgency and age (Pediatric vs. Adult), when appropriate
- Distribution of sequence number of MOT and single organ recipients by match run
- Non-use rate by organ type

Conclusion

The purpose of this proposal is to clarify that organ offer acceptance takes priority over requirements to offer more than one organ to a single candidate. Therefore, if a primary single organ is declined after all organs have been placed, the OPO is not required to allocate to required MOT shares since a second organ is no longer available.

Considerations for the Community

- Should a specific timeframe be included in the policy language? For example, if an organ has been accepted by a transplant program and the donor recovery has been scheduled.
- Should this apply only after all organs are allocated and accepted, including required multi-organ shares?
- Do patients and donor families support the concept that accepted organs take priority over required multi-organ shares?

Policy Language

Proposed new language is underlined (<u>example</u>) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

5.6.D Effect of Acceptance

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.

<u>If an organ has been accepted by a transplant program, that organ is no longer available for subsequent offers, including those according to *Policy 5.10: Allocation of Multi-Organ Combinations*.</u>

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