

Public Comment Proposal

Modify Organ Offer Acceptance Limit

OPTN Organ Procurement Organization Committee

*Prepared by: Robert A. Hunter
UNOS Policy Department*

Contents

Executive Summary	2
Purpose	3
Background	3
Overview of Proposal	7
NOTA and Final Rule Analysis	7
Implementation Considerations	7
Post-implementation Monitoring	8
Conclusion	9
Considerations for the Community	9
Policy Language	10

Modify Organ Offer Acceptance Limit

Affected Policies: 5.6.C Organ Offer Acceptance Limit
Sponsoring Committee: Organ Procurement Organization
Public Comment Period: July 27, 2023 – September 19, 2023

Executive Summary

In 2018, changes to OPTN policy established limits on the number of organ offer acceptances for any one candidate per organ type. OPTN policy was previously silent on the number of acceptances for one candidate and the intent of the policy change was to reduce the number of concurrent acceptances. However, post implementation analysis concluded that "it is not uncommon for centers to enter two concurrent acceptances for a single liver candidate, and decision makers spend hours determining which organ, if any, to accept."¹

The practice of having multiple primary organ offer acceptances can lead to late declines, which can cause logistical issues for OPOs resulting in organ reallocations. This can lead to organ non-use, impact the quality of organs, and may negatively impact donor families with the increase in donor case time.

The OPTN Organ Procurement Organization (OPO) Committee proposes to reduce the number of primary organ offer acceptances from two to one for any one candidate per organ type. It is important to note that limiting the number of primary acceptances does not prevent transplant programs from receiving organ offers or affect their ability to decline and provisionally accept offers as necessary.

¹ Robinson A, Shutterly K, Sellers M, Rosendale J, Brockmeier D. Concurrent Final Acceptance Associated with Decreased Deceased Donor Liver Utilization [abstract]. Am J Transplant. 2020; 20 (suppl 3). <https://atcmeetingabstracts.com/abstract/concurrent-final-acceptance-associated-with-decreased-deceased-donor-liver-utilization/>. Accessed May 15, 2023.

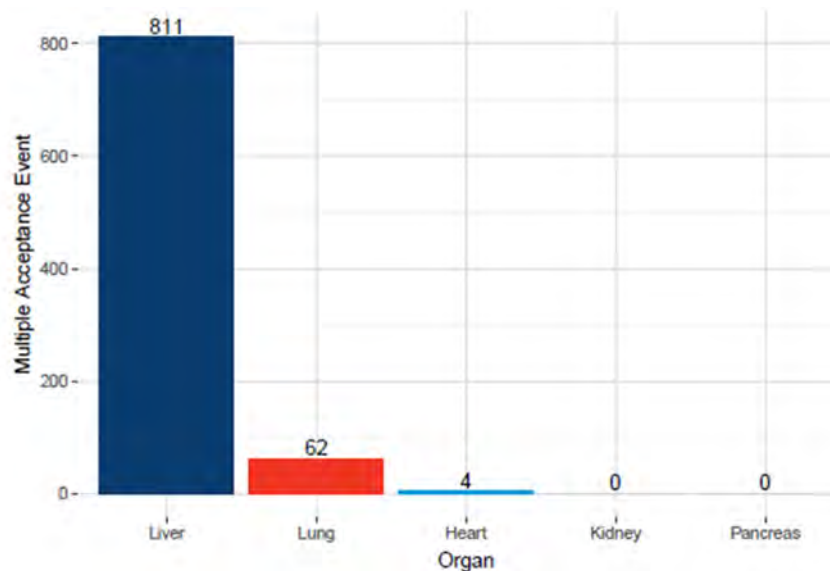
Purpose

The purpose of this proposal is to modify the existing policy that allows two organ offer acceptances, changing it to allow only one organ offer acceptance. This proposed change will eliminate the scenario in which a candidate can have two primary organ offer acceptances from two different OPOs while the transplant program waits to determine which organ to eventually accept. While there may be a variety of reasons for waiting to determine which organ to accept, including the scheduling of donor recovery and additional donor testing, a delay in the final decision on one of the offers prevents the OPO from moving forward with placement of the second organ. Additionally, delays in placement could have a negative impact on other organs the OPO may be trying to place. For example, a donor family may not be willing to further delay the withdrawal of life-sustaining measures.

Background

This proposal was developed to address concerns from the OPO community regarding the practice of transplant programs holding two primary organ offer acceptances for a single candidate and then subsequently declining one late in the process. **Figure 1** shows there were 811 liver concurrent acceptance events over an 18-month period (March 15, 2021 and September 15, 2022), which means there were 1622 livers that needed to be allocated.² However, half of those cannot be placed under the current policy until the transplant program makes a final decision on one of the offers.

Figure 1. Concurrent Acceptances by Organ Type



When OPOs make organ offers to transplant programs using the OPTN Donor Data and Matching System, transplant programs can either electronically decline the offer or enter a provisional yes. These responses are required within an hour as outlined in *Policy 5.6.B: Time Limit for Review and Acceptance of Organ Offers*. When a transplant program has a candidate that is the primary potential transplant recipient, they must make a final decision to either accept or decline the offer. Once accepted, the OPO will enter a final acceptance into the system and begin working with the transplant programs to ensure all testing and additional information is provided. There are currently no policy requirements addressing

² Ibid

how long this process can take due to the complexity and various factors that affect organ placement. Additionally, it should be noted that OPOs could be making offers for up to 8 organs at one time.

If a transplant program is receiving offers from two different OPOs and becomes primary for both, the program could wait to determine which organ(s) to accept for their candidate and refuse the other offer. However, if this is done late in the allocation process it causes logistical challenges for the OPO to reallocate the organ. On average, concurrently accepted livers are declined 1.5 hours before cross clamp and concurrently accepted lungs are declined 5 hours before cross clamp.³ This can lead to organ non-use, impact the quality of organs, and negatively impact donor families with the increase in donor case time. Additionally, when reallocation is required, there is the potential for the other organs from that donor to be affected by the delay in donor recovery.

Table 1 outlines the policy options considered by the Committee to address this problem.

Table 1. Policy Options

Current Policy Language	Options Considered
<p>5.6.C Organ Offer Acceptance Limits For any one candidate, the transplant hospital can only have two organ offer acceptances for each organ type. The host OPO must immediately report transplant hospital organ offer acceptances to the OPTN.</p>	1. Modify <i>Policy 5.6.C: Organ Offer Acceptance Limits</i> to only allow one primary organ offer acceptance
	2. Modify <i>Policy 5.6.C: Organ Offer Acceptance Limits</i> to only allow one primary organ offer acceptance <u>and</u> establish a timeframe for when a transplant program must make a decision on one of the offers
	3. Modify <i>Policy 5.6.C: Organ Offer Acceptance Limits</i> to only allow one primary organ offer acceptance <u>and</u> provide an exception for higher status candidates to have two primary offers
	4. Modify <i>Policy 5.6.C: Organ Offer Acceptance Limits</i> to only allow one primary organ offer acceptance <u>and</u> provide an exception to allow two acceptances if one of the concurrent acceptances is a DCD donor

Feedback from several OPTN Committees, including the Liver and Intestinal Organ Transplantation, Lung Transplantation, Kidney Transplantation, and Transplant Coordinators Committees favored exceptions for higher status candidates with varied support for a timeframe and exception for DCD donors.

The Committee ultimately determined that the best solution was to reduce the number of primary acceptances from two to one without any exceptions. Establishing exceptions for higher status candidates would only reduce the number of concurrent acceptances by 33%.⁴

³ Katrina Gauntt and Cass McCharen, "Multiple Acceptance Data Request," OPTN, Descriptive Data Request for Organ Offer Acceptance Limits Workgroup, February 16, 2023.

⁴ Ibid

1. *Modify Policy 5.6.C to only allow one primary organ offer acceptance*

Limiting primary organ offer acceptances for any one candidate does not prevent transplant programs from receiving additional offers for their candidates or entering a provisional yes on the match run. It also does not prevent transplant programs from declining the current offer if a better offer is received. This proposed change will prevent OPOs from entering a second acceptance on a match run for a given candidate at a transplant program. Instead, the transplant program must decline the first offer prior to accepting the second offer for their candidate.

2. *Modify Policy 5.6.C to only allow one primary organ offer acceptance and establish a timeframe for when a transplant program must make a decision on one of the offers*

The Committee discussed establishing a deadline of 4-6 hours prior to donor recovery time for a transplant program to make a decision on which organ to accept if there are two primary organ offers. This was due to the concern that an organ gets offered and sometimes more than 24 hours will pass before the donor recovery time is set. They acknowledged that it takes time to coordinate offers of other organs and recovery teams, and this does not affect the ability to receive other offers. The Committee did not favor this option because donor recovery time is a moving target due to OPOs coordinating various recovery teams and, if two donors are involved, the factors that determine which donor recovery time would be used may vary.

3. *Modify Policy 5.6.C to only allow one primary organ offer acceptance and provide an exception for higher status candidates to have two primary offers*

This was the option favored by the collaborating committees and would allow higher status candidates to have concurrent primary acceptances. For liver, this was recommended to include Status 1A and 1B candidates as well as those with a MELD⁵ or PELD⁶ score of 35 or greater. For lung, this was recommended to include candidates with a lung allocation score of 50 or higher. The rationale for this recommendation was to not disadvantage the higher status candidates if one of the organ acceptances did not lead to organ recovery and transplant.

However, when a program is holding two primary acceptances for one candidate, it prevents other higher status candidates elsewhere on the match runs from becoming the primary potential transplant recipient. Since medical urgency is a key component of allocation performance goals as outlined in the OPTN Final Rule, higher status patients may actually be disadvantaged by this scenario if, ultimately, an OPO must take extensive measures to place an organ due to a late-turndown just prior to the scheduled organ recovery procedure.⁷ In this case, OPOs may make the decision to bypass medically urgent candidates higher on the match run which happens at a rate more than double the national average, in order to find an acceptor lower down on the match run in order to avoid organ non-use.

Figure 4 shows that 80% of the time, livers turned down as part of concurrent acceptances are allocated to candidates with a MELD/PELD score of less than 34.⁸

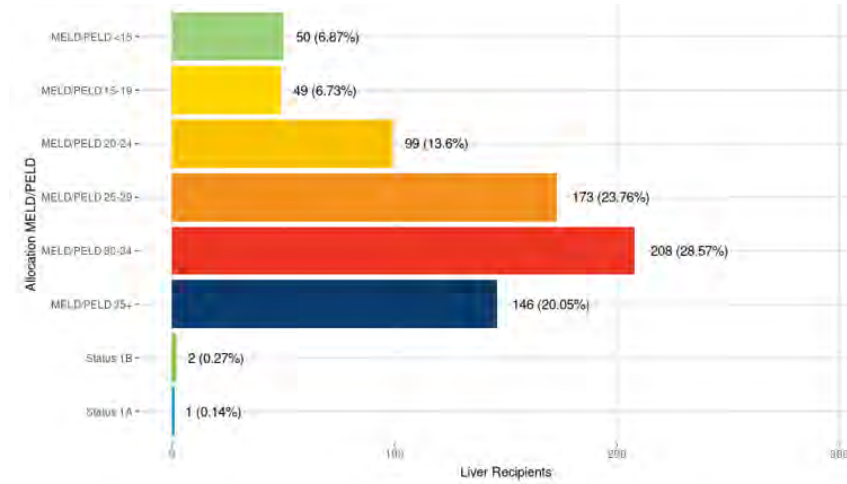
⁵ Model for End-Stage Liver Disease

⁶ Pediatric End-Stage Liver Disease

⁷ 42 CFR §121.8(b)(2)

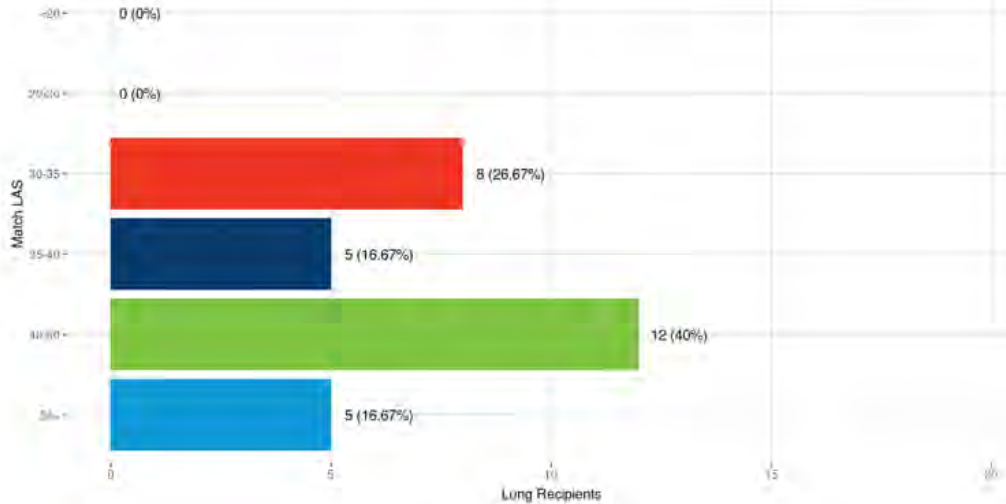
⁸ Katrina Gauntt and Cass McCharen, "Multiple Acceptance Data Request," OPTN, Descriptive Data Request for Organ Offer Acceptance Limits Workgroup, February 16, 2023.

Figure 4. Allocation MELD/PELD of Recipients of Livers Turned Down by Concurrent Acceptors



The same is true for lungs, as **Figure 5** shows that 83% of the time lungs turned down as part of concurrent acceptances are allocated to candidates with a lung allocation score of less than 50.

Figure 5. Lung Allocation Score of Recipients of Lungs Turned Down by Concurrent Acceptors



4. Modify Policy 5.6.C to only allow one primary organ offer acceptance and provide an exception for donation after circulatory death (DCD) donors

The rationale for this exception was to address the scenario where one of the donors in the concurrent acceptance scenario is a DCD donor. The second acceptance would serve as a “backup” in case the DCD donor does not progress to organ recovery. The Committee did not believe the data supported the need for an exception for DCD donors. For concurrent acceptances, only 4.4% (72 of 811) of livers and 11.29% (14 of 62) of lungs involved a DCD donor.⁹

⁹ Ibid

Overview of Proposal

The Committee proposes reducing the number of primary organ offer acceptances from two to one for each candidate per organ type. Current policy allows two acceptances which has led to concerns from the OPO community regarding late turndowns and placement delays. It is important to note that this proposal does not prevent transplant programs from receiving organ offers or eliminate the ability to decline and provisionally accept other organ offers.

NOTA and Final Rule Analysis

The Committee submits the following proposal under the authority of the National Organ Transplant Act (NOTA), which states the OPTN shall “assist organ procurement organizations in the nationwide distribution of organs equitably among transplant patients.”¹⁰ Concurrent acceptances for one candidate reduces access to organs for other candidates who are listed on the same match runs.

In addition, the OPTN Final Rule states “A transplant program shall either accept or refuse the offered organ for the designated potential recipient within such time as the OPTN may prescribe.”¹¹ This proposal would change the policy related to organ offers for potential recipients by reducing the number of concurrent acceptances that transplant programs can have for a single candidate (per organ type) from two to one. The intent is to reduce the number of late turndowns, which currently leads to logistical challenges for OPOs.

The Final Rule also states that allocation policies “shall seek to achieve the best use of donated organs” and “shall be designed to avoid wasting organs...promote patient access to transplantation and promote the efficient management of organ placement.”^{12,13} As noted above, concurrent acceptances for one candidate reduces access to organs for other candidates. Reducing the number of acceptances allows OPOs to move forward with efficient placement of organs.

Implementation Considerations

Member and OPTN Operations

Operations affecting Organ Procurement Organizations

OPOs need to be aware of the policy changes and develop communication strategies to ensure transplant programs are aware when evaluating organ offers.

Operations affecting Transplant Hospitals

Transplant hospitals will need to be aware that in order to accept another organ offer, they will need to decline the current organ offer acceptance.

Operations affecting Histocompatibility Laboratories

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

¹⁰ 42 USC §274(2)(D)

¹¹ 42 CFR 121.7(b)(4)

¹² 42 CFR §121.8(a)(2)

¹³ 42 CFR §121.8(a)(5)

Operations affecting the OPTN

This proposal will involve information technology (IT) implementation efforts in the OPTN Donor Data and Matching System. IT implementation would support the change in policy related to organ offers for potential recipients by reducing the number of concurrent acceptances that transplant programs can have for a single candidate (per organ type) from two to one.

Potential Impact on Select Patient Populations

There is no impact on select patient populations.

Projected Fiscal Impact

Projected Impact on Organ Procurement Organizations, Transplant Hospitals, and Histocompatibility Laboratories

There is no expected fiscal impact for OPOs, transplant hospitals, and histocompatibility laboratories.

Projected Impact on the OPTN

The OPTN will need to update the relevant policies on the OPTN website, as well as communicate the proposed changes to the transplant community and monitor the changes after implementation.

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 deceased donor match runs that result in a transplanted organ to ensure that organs have been allocated according to OPTN policy and will continue to investigate potential policy violations.

Policy Evaluation

The Final Rule requires that allocation policies “be reviewed periodically and revised as appropriate.”¹⁴

This policy will be formally evaluated at approximately 6 months, 1-year, and 2-years post-implementation. The following metrics, and any subsequently requested by the committee, will be evaluated as data become available (appropriate lags will be applied, per typical OPTN conventions, to account for time delay in institutions reporting data) and compared to an appropriate pre-policy cohort to assess performance before and after implementation of this policy, where appropriate. Timeline is subject to change based on the results.

¹⁴ 42 CFR §121.8(a)(7).

As data shows events of concurrent acceptance for kidney or pancreas are rare, the following metrics will be evaluated for Heart, Lung, and Liver:

- The non-use rate (organs recovered with the intent to transplant but not transplanted)
- The proportion of organs with a final acceptance allocated out of sequence or through the expedited liver process
- The number of acceptances refused after cross clamp
- Medical urgency status at transplant for recipients
- Distribution of cold ischemic time at transplant for recipients

Conclusion

In order to reduce late turndowns and provide access to organs for higher status candidates, the Committee proposes reducing the number of primary organ offer acceptances for any one candidate from two to one.

Considerations for the Community

The OPO Committee is seeking input from the community on this proposal.

- Why should transplant programs be allowed to hold two primary acceptances while other candidates are also in need of a lifesaving organ?
- Which options that the committee discussed are you supportive or not supportive of and why?
- Are there other potential options the committee should consider?

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.

1
2
3
4
5

5.6.C Organ Offer Acceptance Limit

For any one candidate, the transplant hospital can only have one ~~two~~ organ offer acceptances for each organ type. The host OPO must immediately report transplant hospital organ offer acceptances to the OPTN.

#