OPTN

Briefing to the OPTN Board of Directors on

Modify Organ Offer Acceptance Limit

OPTN Organ Procurement Organization Committee

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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*
Board of Directors Meeting: *December 4, 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.[1] 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."[2]

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 increases the potential for organ non-use, impacts the quality of organs, and may negatively impact donor families with the increase in donor case time. With the recent focus by the OPTN to improve efficiency in organ placement, this proposal can serve as a small step to improve the efficiency of organ placement by allowing OPOs to move forward with placing organs that are currently held up by concurrent acceptances.[3]

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.

This proposal was issued for public comment from July 27, 2023 to September 19, 2023. The Committee reviewed the public comments and no changes were made to the policy language. The rationale for that decision is discussed below.

[1] https://optn.transplant.hrsa.gov/media/2368/opo_policynotice_20171221.pdf
[2] 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.
[3] https://optn.transplant.hrsa.gov/news/recording-of-optn-task-force-town-hall-regarding-organ-usage-and-placement-efficiency/.

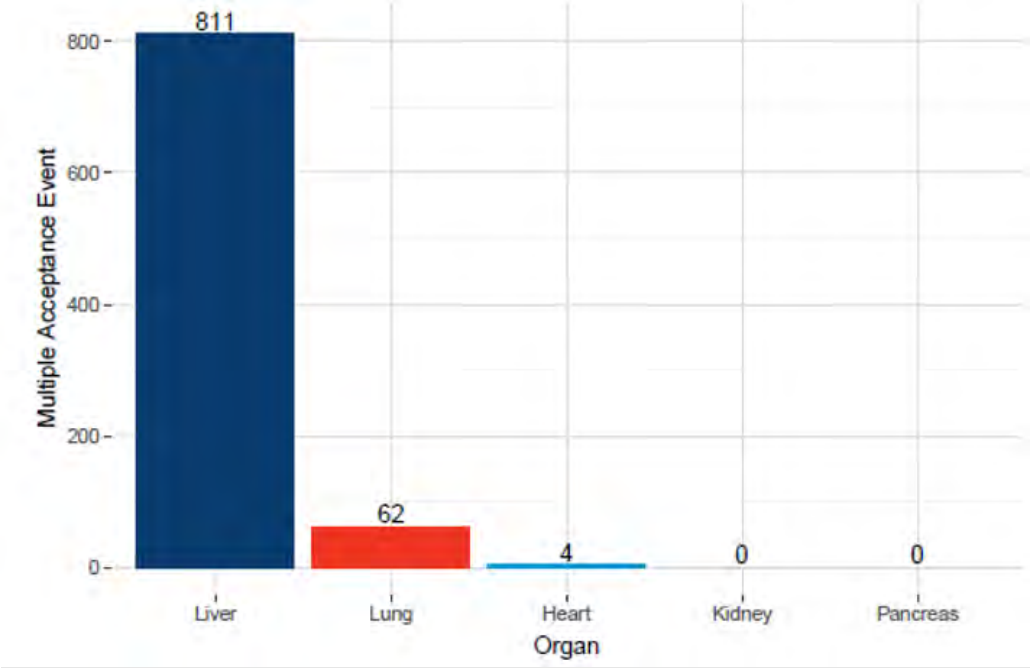
Purpose

The purpose of this proposal is to modify the existing policy that allows two simultaneous 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 considers which organ to ultimately accept, if any. 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 and typically leads to a late turndown. 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 organ recovery procedure.

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.[4] However, half of those could not be placed under the current policy until the transplant program made a final decision on one or both of the offers.

Figure 1: Concurrent Acceptance Events by Organ Type



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

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 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.[5] This can lead to organ non-use, negatively impact the quality of organs, and cause distress on donor families with the increase in donor case time. Additionally, when reallocation is required, there is the potential for all of the other organs from that donor to be affected by the delay in organ recovery.

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

Table 1: Policy Options

Current Policy Language	Options Considered
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.	1. Modify *Policy 5.6.C: Organ Offer Acceptance Limits* to only allow one primary organ offer acceptance
	2. Modify *Policy 5.6.C: Organ Offer Acceptance Limits* to only allow two primary organ offer acceptances and establish a timeframe for when a transplant program must make a decision on one of the offers
	3. Modify *Policy 5.6.C: Organ Offer Acceptance Limits* to only allow one primary organ offer acceptance and provide an exception for higher status candidates to have two primary offers
	4. Modify *Policy 5.6.C: Organ Offer Acceptance Limits* to only allow one primary organ offer acceptance and 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.

[5] Ibid.

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%.[6]

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 decide 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.*

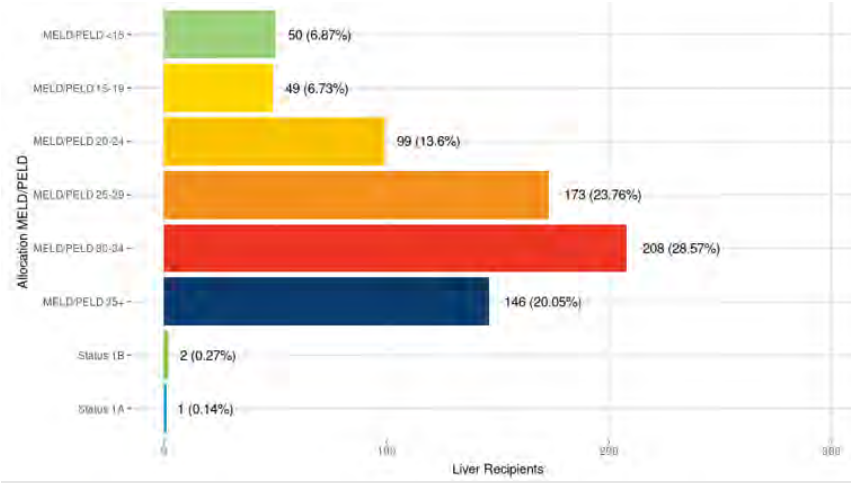
This was the option favored by the collaborating committees and would allow higher status candidates to have concurrent primary acceptances. For liver, this was recommended to include Status 1A and 1B candidates as well as those with a Model for End-Stage Liver Disease (MELD) or Pediatric End-Stage Liver Disease (PELD) score of 35 or greater. For lung, this was recommended to include candidates with a lung allocation score of 50 or higher.[7] 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 all 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.[8] In this case, OPOs need to quickly find an acceptor on the match run to avoid organ non-use. When this happens, the decision to bypass medically urgent candidates to find an acceptor further down the match run occurs at a rate more than double the national average.

[6] Ibid.
[7] Lung allocation score – calculated for candidates aged 12 and older prior to the implementation of lung composite allocation score.
[8] 42 CFR §121.8(b)(2).

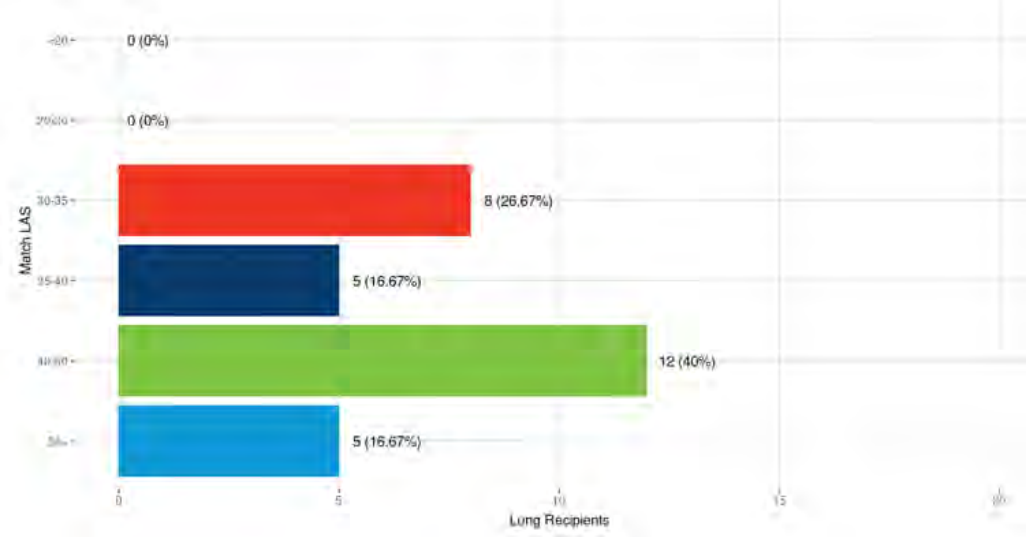
Figure 2 shows that 80% of the time, livers turned down as part of concurrent acceptances are allocated to candidates with a MELD/PELD score of less than 34.[9]

Figure 2. Allocation MELD/PELD of Recipients of Livers Turned Down by Concurrent Acceptors



The same is true for lungs, as **Figure 3** 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 3. Lung Allocation Score of Recipients of Lungs Turned Down by Concurrent Acceptors[10]



[9] Katrina Gauntt and Cass McCharen, "Multiple Acceptance Data Request," OPTN, Descriptive Data Request for Organ Offer Acceptance Limits Workgroup, February 16, 2023.
[10] Ibid – Note: Data request cohort predated implementation of lung continuous distribution.

4. ***Modify Policy 5.6.C to only allow one primary organ offer acceptance <u>and</u> 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% (72 of 811) of livers and 11% (14 of 62) of lungs involved a DCD donor.[11]

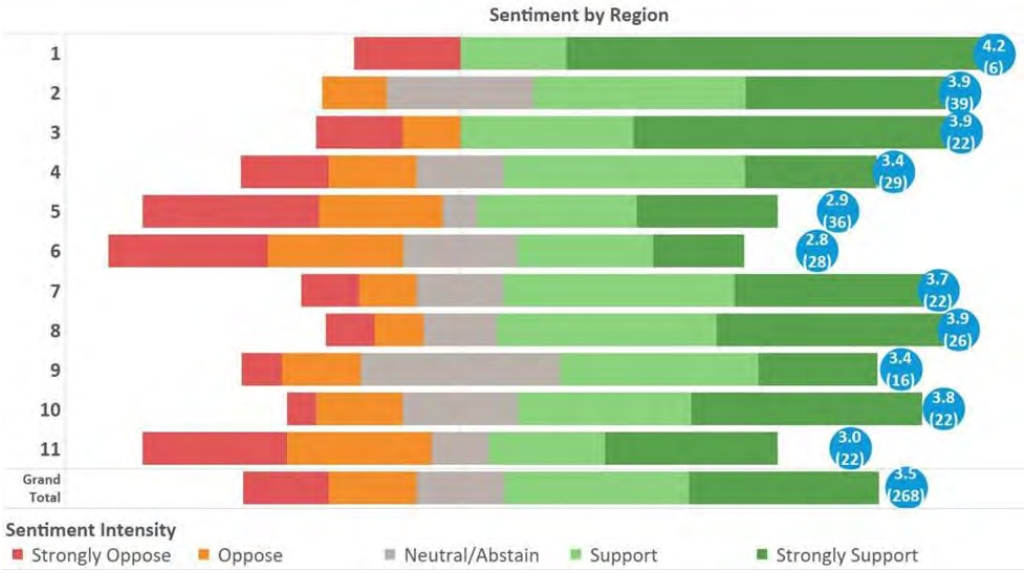
Proposal for Board Consideration

The Committee did not make any post public comment changes. 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. While there were considerable concerns raised during public comment, most notably regarding higher status candidates, the Committee decided to submit the policy proposal to the Board of Directors without post-public comment changes. Further information about the Committee's deliberations and rationale for not making post-public comment changes can be found in the "Overall Sentiment from Public Comment" section.

Overall Sentiment from Public Comment

The overall sentiment for the proposal was favorable but a notable proportion did not support as shown in the following figures. Sentiment by region, as shown in **Figure 4**, shows the overall sentiment score of 3.5.

Figure 4. Sentiment by Region



[11] Ibid.

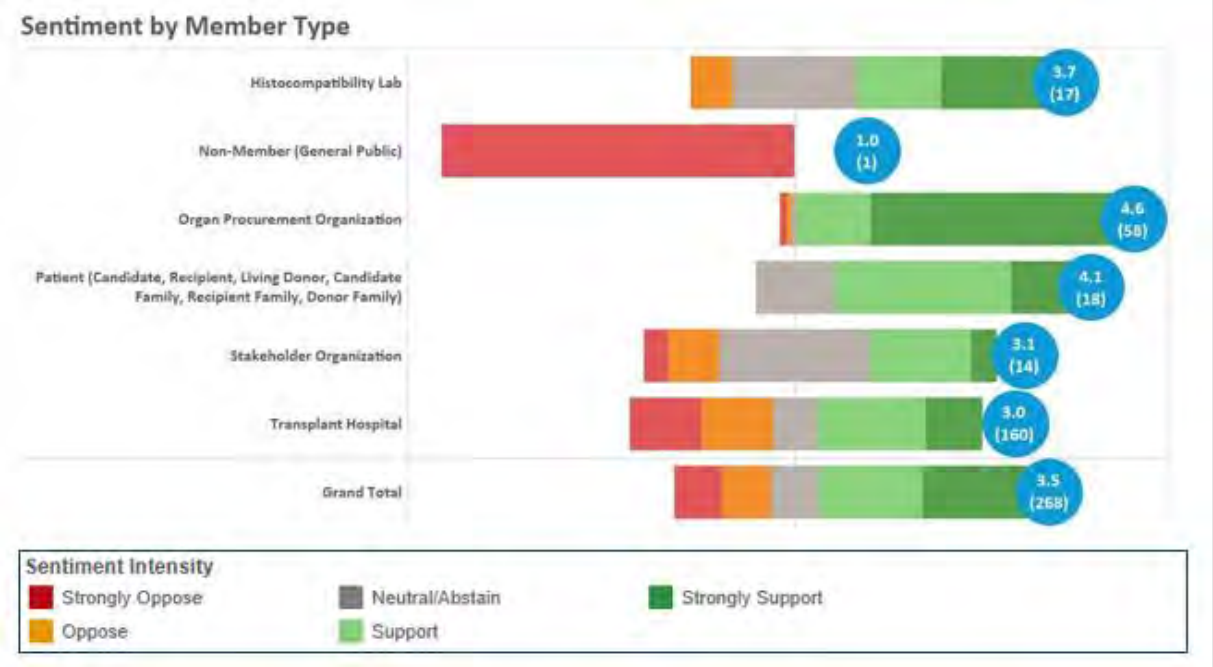
Table 2 provides a more detailed breakdown of the sentiment counts from designated OPTN representatives at the regional meetings. The proposal received 116 votes in support, 41 votes in opposition, and 24 neutral/abstention votes. While there were opposing comments during each regional meeting, there was more support for the proposal and the effort to improve the efficiency of organ placement, reduce out of sequence allocations, and provide access to organs for higher status candidates.

Table 2: Regional Sentiment Votes

Region	Strongly Support	Support	Neutral/Abstain	Oppose	Strongly Oppose	Totals
1	3	1	0	0	0	4 support, 0 oppose, 0 neutral/abstain
2	11	8	3	0	0	19 support, 0 oppose, 3 neutral/abstain
3	9	4	0	2	1	13 support, 3 oppose, 0 neutral/abstain
4	4	10	3	3	3	14 support, 6 oppose, 3 neutral/abstain
5	7	7	1	5	5	14 support, 10 oppose, 1 neutral/abstain
6	3	2	3	3	1	5 support, 4 oppose, 3 neutral/abstain
7	5	6	2	1	2	11 support, 3 oppose, 2 neutral/abstain
8	7	6	3	2	1	13 support, 3 oppose, 3 neutral/abstain
9	2	3	5	2	1	5 support, 3 oppose, 5 neutral/abstain
10	5	5	3	3	0	10 support, 3 oppose, 3 neutral/abstain
11	5	3	1	3	3	8 support, 6 oppose, 1 neutral/abstain
Totals	**61**	**55**	**24**	**24**	**17**	**116 support, 41 oppose, 24 neutral/abstain**

The overall sentiment by member type is shown in **Figure 5**. This figure shows the difference between how transplant programs and OPOs feel about the proposal with 3.0 and 4.6 average sentiment votes, respectively. Additionally, comments received from stakeholder organizations were of differing opinions, with transplant hospital perspectives not in support of the proposal while OPOs were supportive.

Figure 5. Sentiment by Member Type



Comments were mixed in support and opposition for this proposal. In addition to the sentiment score received during the regional meetings, substantive written comments were provided by the regions as well as sixteen organizations, eight stakeholder organizations, nine OPTN Committees, and twenty individuals. Commenters covered many different topics, including the following themes:

- Exception for higher status liver candidates (allow two acceptances)
- Exception for DCD donors (allow two acceptances)
- Concern about impact on pediatrics
- Consider a timeframe for acceptance
- Improve information sharing and communication between OPOs and transplant programs
- Need for timely donor information, including biopsies

Each theme is addressed in the following sections and a complete list of comments can be found on the OPTN website.[12]

Public Comment Themes and Considerations

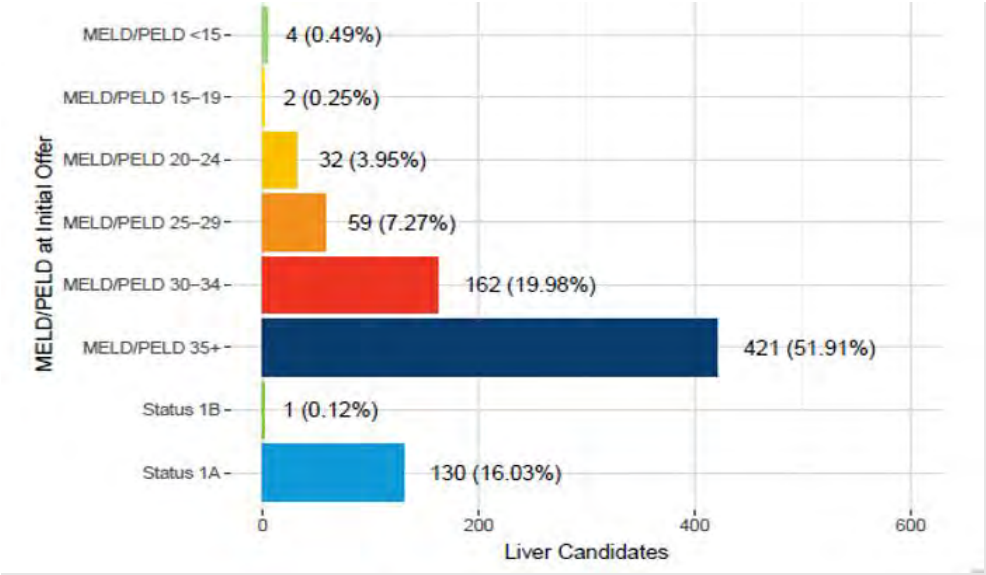
Exception for Higher Status Candidates

This topic was the top concern raised during public comment. Most transplant programs and transplant organizations expressed concern about the impact this proposed change would have on the sicker patients. Most commenters suggested an exception for higher status candidates to allow for two acceptances. The Committee completely understands the urgency of getting higher status candidates transplanted. However, more higher status candidates are being disadvantaged when transplant programs hold concurrent acceptances because it delays or even prevents offers from going to other higher status candidates.

[12] https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/modify-organ-offer-acceptance-limit/.

Almost 70% of the liver candidates with concurrent acceptances were Status 1A/1B or had a MELD/PELD of 35 or greater, as shown in **Figure 6**.

Figure 6. MELD/PELD at Initial Offer Acceptance for Concurrent Acceptors



When one or both offers are subsequently declined, the liver gets reallocated to lower status liver candidates (MELD/PELD less than 35) 80% of the time, as noted previously in **Figure 2**. This practice is contributing to the increase in out of sequence allocations.

This data clearly shows that higher status candidates are disadvantaged. However, it is not the higher status candidates who are part of the concurrent acceptances, it is the higher status candidates who are not afforded an opportunity to receive offers because one transplant hospital is holding two offers.

One of the "considerations for the community" questions included in the proposal was "why should transplant programs be allowed to hold two primary acceptances while other candidates are also in need of a lifesaving organ?" The only response to that specific question was received by the American Society of Transplant Surgeons (ASTS) with the following justifications for opposing this proposed change:

- *Time needed to schedule donor recovery* – The ASTS commented that "the length of time it takes to schedule a donor recovery forces transplant programs to stay with two offers until one of the donor recoveries is scheduled." However, the Committee notes that organ placement takes time especially when there are several organs involved. Additionally, this additional time should afford the transplant programs additional time to evaluate the donor information and prepare the recipient for transplant. Lastly, when one transplant program is holding two primary acceptances, the OPO is not allowed to move forward with placing organs from one of the donors and get donor recoveries scheduled.
- *Higher status candidates* - The ASTS also commented that "the primary recipient is very sick and may die before the OR occurs (status 1 or high MELD or high lung status)." The Committee agrees that higher status patients are very sick, which is even more justification to only allow transplant programs to hold one primary acceptance so that other sick candidates have access to organs. As noted previously in **Figure 2** , the outcome for livers that were transplanted with a

candidate that was not the concurrent acceptor. 80% of the time the liver was reallocated to a candidate with a MELD/PELD score of 34 or less, and not to higher status candidates.

Exception for DCD Donors

This topic received the second most comments during the public comment period. As noted previously in this briefing paper, the Committee did not believe the data supported the need for an exception for DCD donors. For concurrent acceptances, only 4% (72 of 811) of livers and 11% (14 of 62) of lungs involved a DCD donor. The Committee recognizes that DCD donation is increasing each year, particularly with the use of machine and normothermic regional perfusion. However, the Committee noted that transplant programs do not routinely accept DCD donors for their higher status candidates. Of the already low percentage of DCD donors with concurrent acceptances, only 25% of those included higher status candidates.[13]

The Committee agreed that monitoring this change and its impact on DCD donation would be important following implementation. Again, due to the low numbers of DCD donors involved in concurrent acceptances, the Committee does not feel that an exception for DCD donors is warranted at this time.

Impact on Pediatric Candidates

There were several comments regarding the impact on pediatric candidates due to size matching, organ suitability and travel distances. The Committee reviewed data following public comment and noted that only 1.97% of the concurrent acceptances involved a pediatric candidate. The Committee recognizes the importance of the pediatric population but reiterated that transplant programs continue to receive offers regardless of the number of acceptances. Additionally, as is the case with higher status candidates, if two primary organ offers are being held for one pediatric candidate, it is preventing another pediatric candidate from receiving an offer for one of those organs.

Timeframe for Acceptance

There were several comments suggesting a timeframe be placed on a transplant program to decide on which organ to accept if holding two offers, especially if a donor recovery time has been set for one of the offers. The comments noted that an organ gets offered and sometimes more than 24 hours will pass before the donor recovery time is set. However, the Committee noted that it takes time to place other organs and coordinate various recovery teams. Any progress made during this time could be derailed if an organ is subsequently declined. The Committee also agreed that establishing a timeframe would be challenging to put in policy and operationalize. There are two different donor recoveries to coordinate, no mandatory data fields, and donor recovery times are tentative until all logistics have been finalized with the various recovery teams. Therefore, the Committee decided not to establish a timeframe at this time.

[13] Additional data request from Katrina Gauntt and Cass McCharen, "Multiple Acceptance Data Request," OPTN, Descriptive Data Request for Organ Offer Acceptance Limits Workgroup, February 16, 2023.

Improve Information Sharing and Communication

There were several comments about improving information sharing and communication between transplant programs and OPOs. The Committee supports transparency so that both OPOs and transplant programs are actively aware of multiple acceptances. However, the Committee does not believe better communication will prevent late turndowns if transplant programs continue to hold two acceptances.

Additionally, the comments received about OPOs ensuring appropriate backup offers. The Committee appreciates those comments. OPOs typically ensure there are backup offers to avoid organ non-use, but this proposal is intended to address multiple primary offer acceptances and the impact that those acceptances have. Additionally, utilizing backups often results in an out of sequence allocation unless the backup is the next candidate on the match run.

Additional Comments

Patient perspective

The patient voice is an important aspect of every policy discussion. While this proposal did not receive a lot of comments from the patient perspective, it is important to highlight a couple of public comments received about this proposed change.[14]

- "As a two-time transplant patient, ten years apart, I would like nothing more than for me and my medical team to have the luxury of simultaneous choice between two organs. However, I would not desire such a choice if there is an undue risk that another patient is not able to undergo a transplant as a result."
- "With so many people waiting on organs, it seems a travesty that this would not have been the policy all along. One unused organ is one too many. This action should help in the drive to increase the donor base if the public is assured organs will not be wasted."
- "Candidates with medical urgency are being bypassed and disadvantaged due to late declines from concurrent offer acceptance due to the urgency of placing an organ with back up candidates or candidates who are readily available."

Need for timely donor information, including biopsies

There were several comments about the timing of deceased donor information, including biopsies. The Committee supports any effort to provide as much information as possible for transplant programs to make decisions on offers. *OPTN Policy 2.11: Deceased Donor Information* addresses the required information that must be provided by OPOs, and transplant programs can request additional information if needed. However, it should be noted that lack of donor information was not a top reason for why transplant programs decline one of the concurrent acceptances. The top three reasons a recovered liver that was part of a concurrent acceptance was subsequently declined were the following:

- Candidate transplanted/pending transplant (49.5%)
- Candidate ill/unavailable/refused/or temporarily unsuitable (15.84%)
- Donor age/quality (9.68%)

[14] https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/modify-organ-offer-acceptance-limit/.

OPO perspective

The OPO community is overwhelmingly in favor of this proposed change and emphasized that any policy change that improves the organ placement system should be approved and implemented. The following comments illustrate the challenges created by the current policy and support the need for change:

- "We appreciate that any system in which donated organs fall short of helping every patient on the waitlist, measures will be taken to attempt to be fair and equitable. We do not believe the ability to accept two organs simultaneously has provided any relief; rather, it has unnecessarily complicated an already complex process to allocate organs."
- "When transplant centers accept multiple organs, this creates late declines of organs. Late declines often lead to loss of opportunity for transplant of the organ. This causes complications for transplant team coordination and may lead to increased allocations out of sequence and/or organ discard. Acceptance of two organs for one recipient can also result in increased case times and an unnecessarily increased workload for the system."
- "Our OPO has experienced ten late declines on allocated livers through mid-August 2023 that we thought we had placed. All of these were for patients whose centers simultaneously accepted two livers."
    - "Because of a robust and vigilant internal back-up allocation protocol we have in place, we were able to successfully reallocate six of the declined livers with local patients. This protocol unfortunately gives "evidence" to those who say that "liver transplants have increased;" however, it is a workaround that circumvents OPTN policies. We are forced to develop these workarounds, and to expend the increased time, energy, and resources to literally duplicate allocation efforts in order to try to save a viable organ."
    - "In three other cases the late-declined livers went to research facilities because a suitable candidate was not identified in time. There is no reason to believe these organs were unsuitable for transplantation, but the late turn-down severely limited our ability to place them."
    - "Finally, one liver was discarded because we could find neither a recipient nor a researcher in time."

Impact on the system

The practice of holding two acceptances creates issues with the entire organ placement process. There is an impact on OPOs, transplant hospitals, donor hospitals, patients, and donor families. The following comments highlight the impact on the various parties, particularly the donor families:

- "Transplant center acceptances of multiple organs for the same candidate creates extreme systemic challenges, one of which is a late decline of the organ when the decision is made to accept one organ over the other. Late declines create significant downstream challenges that jeopardize the entire donation process. Late declines result in OPOs pausing the donation case to re-allocate the organ which can result in other transplant teams canceling flights and then scrambling for transportation options later. Late declines create undue stress on the donor family and strain ICU hospital resources to maintain the donor until the organ is placed and all accepting centers and the OPO can align on another recovery time. In some cases, the late decline comes during the donor OR, and the donor OPO must re-allocate the organ in question, often bypassing sicker patients who could have benefited from the transplant, but who cannot now receive the organ because of the short notice and prolonged cold ischemic time. Late

declines create a significant risk of organ non-use. We note that out of sequence allocation occurs at nearly double the rate in concurrently accepted organs as in baseline cases."

- "Coordinating organ recovery often poses serious logistical challenges, especially when multiple organs and teams are involved. There are often strict limits from families who restrict the amount of time an OPO is allowed to facilitate donation. Furthermore, hospitals (and OPOs) continue to face staffing challenges in the endemic phase of the COVID-19 pandemic, often severely limiting operating room and staff availability."

Compliance Analysis

NOTA and OPTN Final Rule

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."[15] 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."[16] 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 OPTN Final Rule also states that the OPTN "shall be responsible for developing…policies for the equitable allocation for cadaveric organs."3 Reducing the number of concurrent acceptances a transplant program can have for a single candidate may impact the efficiency of allocation, resulting in more organs being placed sooner, which could lead to more candidates receiving organ offers according to the match run.

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."17 This proposal:

- **Is based on sound medical judgment**[18] because it is an evidenced-based change relying on the following evidence:

[15] 42 USC §274(2)(D).
[16] 42 CFR 121.7(b)(4).
[17] 42 CFR 121.8.
[18] 42 CFR 121.8(a)(1).

  - Data shows that livers reallocated following a late turndown are placed with lower status liver candidates (MELD/PELD less than 35) 80% of the time and lungs reallocated following a late turndown are placed with lower status lung candidates (lung allocation score less than 50) 83% of the time.
- **Seeks to achieve the best use of donated organs[19] by** ensuring organs are allocated and transplanted according to medical urgency.
- **Is designed to avoid wasting organs[20] by** reducing the number of late turndowns due to transplant programs holding two primary acceptances until late in the organ placement process. Late turndowns increase the chances of organ non-use.
- **Is designed to…promote patient access to transplantation[21] by** giving similarly situated candidates equitable opportunities to receive an organ offer. When transplant programs hold two primary acceptances for one candidate, it prevents other higher status candidates from receiving a primary organ offer while that transplant program makes a decision on one or both of their offers.
- **Promotes the efficient management of organ placement[22] by** allowing OPOs to move forward with the allocation of organs from a donor that might currently be delayed by concurrent acceptances for one candidate. This proposal will also help reduce late turndowns which leads to logistical challenges for OPOs and the potential for organ non-use or out of sequence allocations.
- **Is not based on the candidate's place of residence or place of listing.[23]**

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient.[24]

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:

- Is designed to avoid futile transplants.
- Not specific to an organ type, as this policy would apply to all organ types.

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.[39] There is no particular group of candidates impacted by this proposed change to be considered for transition procedures.

OPTN Strategic Plan

Reducing the number of organ offer acceptances aligns with the OPTN strategic plan goal to increase the number of transplants by creating efficiency in the organ placement process. The current policy allowing for two primary acceptances prevents the OPO from moving forward with placement of one of the organs. The proposed policy is intended to reduce the number of late turndowns, out of sequence allocations, and the potential for organ non-use.

[19] 42 CFR 121.8(a)(2).
[20] 42 CFR 121.8(a)(5).
[21] Ibid.
[22] Ibid.
[23] 42 CFR 121.8(a)(8).
[24] 42 CFR 121.8(a)(3).

This proposal also aligns with the OPTN strategic plan goal of providing equity in access to transplants, especially for higher status candidates who could miss out on offers when OPOs are forced to reallocate organs due to a late turndown.

Implementation Considerations

Organ Procurement Organizations

Operational Considerations

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

Fiscal Impact

There is no expected fiscal impact for OPOs.

Transplant Programs

Operational Considerations

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.

Fiscal Impact

There is no expected fiscal impact for transplant hospitals.

Histocompatibility Laboratories

Operational Considerations

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

Fiscal Impact

There is no expected fiscal impact for histocompatibility laboratories.

OPTN

Operational Considerations

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.

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.

Resource Estimates

The OPTN contractor estimates 690 hours for implementation. This will include an update to modify the logic in the OPTN computer system to allow for only one acceptance per candidate for all organs on all allocation types. Additionally, data transition reporting and communication of system notices, targeted member emails, new articles, training and education, a tool kit, FAQ, and web design.

The OPTN contractor estimates 215 hours for ongoing support. Ongoing support will include staff education and process development for allocation staff reviewing matches. It will also include time dedicated to both a six-month and one-year monitoring report.

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."[25]

This policy will be formally evaluated at approximately 3 months, 6 months, and 1-year 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.

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

- The non-use rate (organs recovered with the intent to transplant but not transplanted)
    - Overall and stratified by donor type (DCD or DBD)
- The utilization rate
    - Overall and stratified by donor type (DCD or DBD)
- 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
    - Overall and stratified by refusal code

[25] 42 CFR §121.8(a)(7).

- Medical urgency status at transplant for recipients
    - Overall and stratified by recipient age
- Distribution of cold ischemic time at transplant for recipients
- Pre-transplant mortality rates
    - Overall and stratified by candidate medical urgency status and candidate age

Conclusion

This proposal will 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.

While there were significant comments in both support and opposition for this proposal, the main goals of this proposal are to reduce late turndowns and out of sequence allocations, decrease the risk of organ non-use, and provide access to organs for patients in need of a transplant. This proposal can also serve to improve the efficiency of organ placement by allowing the OPO to move forward with placing the second organ that is currently being held as part of a concurrent acceptance.

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.

5.6.C Organ Offer Acceptance Limit

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

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