

**OPTN Organ Procurement Organization Committee
Organ Offer Acceptance Limit Workgroup
Meeting Summary
February 16, 2023
Conference Call
David Marshman, Workgroup Chair**

Introduction

The Organ Offer Acceptance Limit Workgroup met via Citrix GoToMeeting teleconference on 02/16/2023 to discuss the following agenda items:

1. Project Purpose
2. Data Request Report
3. Policy Options
4. Reminders

The following is a summary of the workgroup's discussions:

1. Project Purpose

Staff reminded the workgroup members of the background and purpose of this project. The goal is to modify policy to only allow a transplant hospital to have one organ offer acceptance for each organ type for any one candidate. This will eliminate the scenario where a transplant program can be primary for offers from two different OPOs and waiting to determine which organ(s) to accept for their candidate.

2. Data Request Report

Staff mentions that the purpose of the data request was to quantify the extent concurrent acceptances are occurring and the outcome of organs that are concurrently accepted.

Data summary:

Research staff outlined the methods used for the data report:

- Concurrent acceptance events for liver, kidney, pancreas, heart and lung between March 15, 2021 and September 15, 2022
- A concurrent acceptance was defined as a single candidate accepting ('Y') two offers from different donors for the same organ type at the same time
- Acceptance time frames were defined as time from acceptance to the first of the following:
 - Decline (response of 'N')
 - Cross clamp
 - Match complete date
 - The last update prior to when match run completed date was added
 - To avoid the gaps between final actions in the match run and when users came back, sometime days later, and set the completed date.

Research staff presented the components of the data request:

- The number of organs concurrently accepted
- The dispositions of organs with a concurrent acceptances
 - Not Recovered, Recovered Not for Transplant, Discarded, Transplanted to Concurrent Acceptor, Transplanted to Another Candidate
- The refusal reasons for organs declined in a concurrent acceptance events
 - Time of refusal in comparison to time of cross clamp
 - Did refusal lead to an out of sequence placement (861, 862, 863 bypass)
 - Cold ischemic time for organs transplanted
- The discard reasons for organs discarded with a concurrent acceptances
- Medical urgency status of the concurrent acceptor at time of offer (Heart status, MELD or PELD, or LAS)

Research staff noted that due to the distribution of concurrent acceptance events by organ the data was presented in two groups by organ type, thoracic (heart and lung) and liver. Research staff also noted there were no concurrent acceptance events for kidney or pancreas.

Highlights of the data report include:

Concurrent Acceptance Events

- Overall - The highest number of concurrent acceptances was for liver with 811 events. There were no concurrent acceptances for kidney and pancreas.
- Lung - The majority of the concurrently accepting candidates had an LAS of 50 plus at the time of the initial offer acceptance in that concurrent acceptance events often currently accepted candidates or either status one or status to at first offer.
 - Of the 62 candidates, four of them were pediatric, and did not have LAS reported at match.
- Liver – 60% of concurrent acceptances had a MELD/PELD score of greater than 35 or were Status 1A or 1B.

Outcomes - Thoracic

- Thoracic – 34.68% (43) of lungs concurrently accepted were transplanted with the acceptor while 25% (2) of hearts accepted were transplanted with the acceptor. Staff noted that due to the small numbers for hearts, the analysis is focused on lungs.
- Lung – Top refusal reasons for recovered lungs concurrently accepted then declined:
 - 38.89% - Candidate transplanted or pending transplant
 - 13.89% - Organ size, specify
 - 11.11% - Donor age or quality
- Lung – On average, concurrently accepted recovered lungs were declined around 5 hours before cross clamp.
- Thoracic – 97% of concurrently accepted then declined lungs were place according to the match run.
- Lung - Cold Ischemic Time in Hours for Transplanted Lungs Concurrently Accepted then Declined vs Those Accepted and Transplanted with the Acceptor – these showed similar results with 5.4 hours and 5.3 hours respectively.

Outcomes – Liver

- 35.02% (568) of livers concurrently accepted were accepted with the acceptor while 50.74% (823) were transplanted with another candidate.
- Discard Reasons for Livers Concurrently Accepted that were Recovered with the Intent to Transplant but not Transplanted:
 - 28.75% (23) “other specify
 - 27.5% (22) biopsy findings
 - 17.5% (14) “no recipient located – list exhausted.”
- Top Refusal Reasons for Recovered Livers Concurrently Accepted then Declined:
 - 49.5% (450) - Candidate transplanted or pending transplant
 - 15.84% (144) - Candidate ill, unavailable, refused, or temporarily unsuitable
 - 9.68% (88) - Donor age or quality
 - 5.61% (51) - Other, specify
 - 3.19% (29) - Unacceptable organ specific test results, specify
 - 3.08% (28) - Donor size/weight
 - 2.09% (19) - Organ size, specify
 - 1.76% (16) - Candidate’s condition improved, transplant not needed
 - 1.76% (16) - Biopsy results unacceptable
 - 1.1% (10) – Resource time constraint (OPO, TXC, donor hospital, etc)
- On average, concurrently accepted recovered livers are declined around 1.5 hours before cross clamp.
- Placement Process for Recovered Livers Concurrently Accepted then Declined
 - 84.01% (762) using match run
 - 15.99% (145) out of sequence allocation
- Cold Ischemic Time in Hours for Transplanted Liver Concurrently Accepted then Declined vs Those Accepted and Transplanted with the Acceptor – these showed similar results with 6 hours and 5.72 hours respectively.

Conclusions

- Concurrent acceptance event most frequently occur for liver (811)
- The majority of candidates that concurrently accept organs are highly medically urgent (LAS 50+, PELD/MELD 35+, Heart Status 1 or 2)
- Lungs concurrently accepted are most frequently transplanted with acceptor
- The majority of livers concurrently accepted are transplanted with another candidate
- For lungs and livers declined by concurrent acceptors the most frequently occurring refusal reason is “Candidate transplanted or pending transplant”
- On average, lungs are declined around 5 hours before cross clamp and 12 hours before for those transplanted to another candidate
- On average, livers are declined around 1.5 hours before cross clamp and 2 hours before for those transplanted to another candidate
- Out of sequence bypass codes are utilized 16% of the time for livers concurrently accepted then declined that is almost double the national rate for all accepted liver
- The cold ischemic time for transplanted livers that were declined by the concurrent acceptor was slightly longer than those that were transplanted with the concurrent acceptor (6 vs 5.72 hours)

Summary of discussion:

The Chair noted the highest rates of concurrent acceptances occurs with liver. He added that only 16% of livers were placed out of sequence which implies that OPOs are doing a good job of placing livers according to the match run.

A member expressed concern that over 50% of the livers concurrently accepted are transplanted with another candidate and not with a candidate that was one of the concurrent acceptors. The Chair added that based on the data, there were at least two candidates a day negatively impacted by a simultaneous liver acceptance.

A member commented that one positive note from the data is the low liver discard rate for concurrent acceptances. Another member added that the low discard rate is due to the efforts of the OPO to have multiple backup plans to ensure that discard rates for all organs are kept as low as possible. Another member added that OPOs have developed so many work arounds that it is difficult to how inefficient the system is.

A member asked if proposed policy should be considered for all organs or should it focus on the inefficiencies with liver. He added that the inefficiency of the system could be creating disadvantages to some candidates.

A member noted that the availability of recovery surgeons might be having an impact on the process. For example, not many lung programs are willing to accept organs recovered by another surgeon, lung teams typically send their own teams to perform the recovery. Another member added that, particularly for a marginal organ, having the trust that the surgeon is not just going to recover the lungs, but evaluates the quality of the lungs.

He noted that the data shows that lungs with concurrent acceptances are declined well in advance of cross clamp. He opined this might be because information needed to make a decision on lung offers is available much earlier.

A member noted that OPOs have different practices when it comes to providing the information needed for organ offers. He added that willingness to perform abdominal imaging or a bedside liver biopsy varies across OPOs, and final decisions on the liver might not occur until the donor recovery. Lastly, he asked if there was a way to standardize some of the pre-recovery evaluation for liver in an effort to reduce the rates of non-use.

A member noted that transplant programs are not making decisions on livers until they either visualize the organ in the donor operating room or even as late as receiving it at the recipient center. The data does not show a lot of organ non-use because OPOs are doing what needs to be done to mitigate cold ischemic time. She added that it's more of a decision issue than an organ quality issue, and the inability to get a final decision earlier is having an impact on OPOs and other patients waiting for a liver.

A member asked if there was a way to look at the geographical differences to see if there are any identifiable trends. Another member questioned if that would have an impact on the policy decisions being made by the workgroup. Lastly, a member commented about how policy changes might be impacted by future continuous distribution policies.

A member asked for clarification that if a transplant center has accepted two offers for a candidate, will that candidate be excluded from subsequent match runs. OPO staff noted that offers will still be received, and the transplant center just needs to decline one of their existing two and enter a provisional yes acceptance for the third offer.

A transplant center member commented that unless the policy changes, then transplant centers will continue to accept concurrent offers. An OPO member responded that transplant centers inform OPOs of this policy all the time.

The Chair noted that this policy was developed because there was not previously a policy in place addressing the number of acceptances. An unintended consequence is that is the operational inefficiencies created by transplant centers holding onto two primary acceptances before deciding about which one to decline. He added that the decline often occurs late in the process which leaves OPO scrambling to reallocation the second organ.

A member added that the policy doesn't include a timeframe for when the second organ needs to be released.

A member noted that the simple solution is to change the policy and only allow transplant programs to accept one organ per patient.

3. Policy Options

Staff offers outlined the policy options based on previous discussions by the workgroup. This included modifying the current *Policy 5.6.C: Organ Offer Acceptance Limit* (shown below) to only allow one organ offer acceptance. This would not include provisional yes acceptances and it does not prevent additional organ offers from being received.

- *5.6.C: Organ Offer Acceptance Limit:* 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.

Staff reminded the workgroup members that another option being considered is establishing a timeframe prior to scheduled donor organ recovery to decide on one of the organ offers if there is more than one for a candidate.

Staff noted that the workgroup had previously discussed whether medical urgency should be considered. However, based on the data presented, many of the concurrent acceptances are for candidates with higher medical urgency status.

Next Steps:

Staff requested that workgroup members review the policy options outlined on the slides prior to the next workgroup call. This will allow the workgroup to spend more time weighing the various options to identify the appropriate path forward.

Upcoming Meeting

- March 9, 2023

Attendance

- **Workgroup Members**
 - David Marshman
 - PJ Geraghty
 - Errol Bush
 - Gregory Abrahamian
 - Joseph Dinorcia
 - Julie Bergin
 - Kelsey McCauley
 - Larry Suplee
 - Melissa Walker
 - Pablo Sanchez
 - Samantha Endicott
- **HRSA Representatives**
 - Marilyn Levi
- **SRTR Representatives**
 - Katherine Audette
 - Nicholas Wood
- **UNOS Staff**
 - Robert Hunter
 - Katrina Gauntt
 - Lauren Mauk
 - Julia Foutz
 - Kevin Daub