Staff Summary
Hospital 06432N reported that OPO 01072N failed to offer lungs to a heart-lung recipient on two separate occasions

Please note that this accompanying summary information is included to only supplement the original documentation, and assist the Committee members in their thorough review of the source documentation provided in the site survey, desk review or case investigation packet.

Please review the summary of potential policy violations and corrective action plans submitted to determine if a policy violation exists, to determine if the corrective action plan addresses the problem, and to identify an appropriate recommended action.

Possible Action (based on historical MPSC action in similar cases):

- Notice of Noncompliance for Policies 6.5.F and 6.6.F.i.

Staff Summary: In October 2018, OPO 01072N offered a heart to PTR #41 on the HR/LU match at Hospital 06432N who needed heart and lungs. Hospital 06432N requested the lungs, but OPO 01072N reported that they had been placed and refused Hospital 06432N's request that the OPO rescind the lung offer. In February 2019, OPO 01072N offered a heart to PTRs #19 and 20 (same candidate) on the HR/LU match at Hospital 06432N, who also needed lungs. Hospital 06432N requested the lungs but OPO 01072N reported that they had been placed and refused Hospital 06432N's request that the OPO rescind the lung offer. Both sets of allocated lungs went to local Hospital 37788N. A root cause analysis of these events was not performed.

OPO 01072N provided corrective actions including that placement staff will enter code 898 and specify that the center refused when a center refuses to provide or confirm decline codes.

Relevant Policies:
6.5.F Allocation of Heart-Lungs: "When a heart-lung candidate is allocated a heart, the lung from the same deceased donor must be allocated to the heart-lung candidate." (Policy in effect prior to October 18, 2018)

6.6.F.i Allocation of Heart-Lungs from Deceased Donors at Least 18 Years Old: "If a heart or heart-lung potential recipient (PTR) requires a lung, the OPO must offer the lungs from the same deceased donor to the heart or heart-lung PTR according to Policy 6.6.D: Allocation of Hearts from Donors at Least 18 Years Old." (Policy in effect as of October 18, 2018)

MPSC History:

- February 2019: Notice of Noncompliance for a kidney laterality labeling error.
- March 2018: Notice of Uncontested Violation for a hemodilution calculation error.
- March 2018: Letter of Warning for a kidney laterality labeling error.
- October 2017: Notice of Uncontested Violation for a late report of a positive Chagas result.
- July 2017: Notice of Uncontested Violation for an external kidney packaging error.
- July 2017: Released from Letter of Warning and monitoring for an internal packaging violation from October 2016.

Survey information: A routine on site survey of the OPO occurred on April 10-11, 2018. The OPO had a clinical score of 96 percent and a few administrative errors. The MPSC reviewed the results of the survey at its meeting in October 2018 and closed the review with no action.

OPO Volumes

Year	Donors Recovered	Organs Recovered
2016	414	1,423
2017	381	1,391
2018	391	1,365
2019	172*	642*

*As of June 28, 2019.

Historical MPSC actions: The MPSC would typically issue a Notice of Noncompliance in cases involving allocation policy violations. The MPSC has considered higher actions (Letter of Warning, etc.) if the member has a significant compliance history, if the nature of the violation poses a significant patient safety risk, if the member did not adequately correct the root cause of the violation, etc.

Reviewer Comments:

Reviewer 1: I agree with Notice of Noncompliance for Policies 6.5.F and 6.6.F.i.

Reviewer 2: I am not clear why this is a policy violation at all? The sequence of allocation appears to be that the OPO appropriately allocated lungs and then later in the allocation process the ctr with a heart candidate needing lungs requested the OPO rescind the prior lung offer? This seems like an inappropriate request by the ctr. Will that behavior be addressed by the MPSC? My question for the OPO is, in these circumstances where heart allocation has to resume after lungs have been placed, why is the OPO offering a heart to a candidate listed as needing heart/lungs? If the lungs are no longer available, those candidates should be screened off to avoid this type of frustrating circumstance. I think this case should be closed with no action and I think there should be correspondence back to the Ctr about making requests for OPOs to rescind offers.

Reviewer 3: Agree with notice of noncompliance for applicable policies.

Issue Involves: OPO 01072N
Issue Reported by: Hospital 06432N

Issue: Hospital 06432N reported this event through the Improving Patient Safety Portal. In October 2018, OPO 01072N offered a heart to PTR #41 on the HR/LU match at Hospital 06432N who needed heart and lungs. Hospital 06432N requested the lungs, but OPO 01072N reported that they had been placed and refused Hospital 06432N's request that the OPO rescind the lung offer. In February 2019, OPO 01072N offered a heart to PTRs #19 and 20 (same candidate) on the HR/LU match at Hospital 06432N, who also needed lungs. Hospital 06432N requested the lungs but OPO 01072N reported that they had been placed and refused Hospital 06432N's request that the OPO rescind the lung offer.

Relevant OPTN Policies:
6.5.F Allocation of Heart-Lungs: "When a heart-lung candidate is allocated a heart, the lung from the same deceased donor must be allocated to the heart-lung candidate." (Policy in effect prior to October 18, 2018)

6.6.F.i Allocation of Heart-Lungs from Deceased Donors at Least 18 Years Old: "If a heart or heart-lung potential recipient (PTR) requires a lung, the OPO must offer the lungs from the same deceased donor to the heart or heart-lung PTR according to *Policy 6.6.D: Allocation of Hearts from Donors at Least 18 Years Old*." (Policy in effect as of October 18, 2018)

Relevant Correspondence:
Inquiry to OPO 01072N - sent on February 13, 2019
Response from OPO 01072N - received on February 20, 2019
Second Response from OPO 01072N - received on February 27, 2019
Notification letter to OPO 01072N - sent on March 8, 2019

Member Response:

OPO 01072N reported:

- For the October 2018 allocation:
  - Lungs were placed for PTR #3 from the standalone lung match to local Hospital 37788N.
  - The heart allocation had not yet started due to donor pressor requirements. OPO 01072N waited to obtain an echo to allow the donor to stabilize hemodynamically. Lungs were allocated prior to obtaining the echo.
  - Local hospital 37788N accepted the heart for PTR #1, but declined approximately two hours later and OPO 01072N continued with heart allocation.
  - Hospital 06432N entered a provisional yes for PTR #41, who also needed lungs, and when notified they were primary, requested the lungs. OPO 01072N informed Hospital 06432N that they had allocated and placed them the day before.
  - Hospital 06432N requested the OPO contact the lung center and ask them to decline the lung offer, and the OPO informed them this would be a violation of OPTN policy.

  - After numerous conversations with Hospital 06432N wherein OPO 01072N refused to rescind the lung offer, Hospital 06432N declined and OPO 01072N allocated the heart to PTR #42 at a different center.
  - Given the high pressor requirements, and that all heart recipients status 1 and status 2 in Zone A did not require lungs, the decision was made to begin lung allocation prior to obtaining the echo.
- For the February 2019 allocation:
  - Local Hospital 37788N provisionally accepted the heart for PTR #5, pending crossmatch. The OPO made backup offers for PTRs #6 and #7.
  - About an hour later, Hospital 37788N accepted a lung/kidney offer for PTR #2.
  - Hospital 37788N received positive crossmatch results for PTR #5 and declined the heart approximately nine hours later. PTRs #6 and #7 also declined the heart and OPO 01072N restarted allocation.
  - Hospital 06432N received a primary heart offer for PTRs #19 and #20, who also needed lungs. Hospital 06432N requested the lungs and OPO 01072N reported that they placed the lungs prior to the heart being declined by the primary evaluating center.
  - Hospital 06432N requested the OPO contact the lung center and ask them to decline the lung offer, and the OPO informed them this would be a violation of OPTN policy.
  - After numerous conversations with Hospital 06432N wherein OPO 01072N refused to rescind the lung offer, Hospital 06432N reported that they would code out for their center.
  - Six hours after the initial offer and after multiple attempts to contact Hospital 06432N to get them to enter their refusal code without response, OPO 01072N entered code 830 for the center. OPO 01072N was unable to place the heart and reported that these unnecessary delays led to organ wastage.
  - Delaying the lung allocation for potential heart/lung candidates in Zone B would have caused unnecessary delays in this case.
- UNOS staff requested documentation of communication between OPO 01072N and evaluating heart centers whose PTRs also required lungs, but OPO 01072N declined to provide information "requested from a position by the complaining center of assuming ill will or intentional or accidental avoidance of allocation policy, such as logs or recordings of all communications." In a follow-up request for additional clarifying information, UNOS staff followed up on this request, encouraging OPO 01072N to send documentation of communication that the OPO believed would help highlight or explain the OPO's efforts during this time. In the follow-up response, OPO 01072N declined sending any "recordings or stuff that is tangential unless absolutely necessary" and included a communication to staff wherein OPO leadership stressed the need to ensure UNOS staff "is not trying to go after local Hospital 37788N..."
- A root cause analysis was not performed.

OPO 01072N corrective actions:

- When a center refuses to provide or confirm decline codes, placement staff will enter code 898 and specify that the center refused.

SFC OPTN Hearing
Exhibit J.70

Confidential Information

Printed 2/7/2019 1:50:42 PM

Improving Patient Safety

Safety Situation Details

Situation ID 101555 **Reported 02/07/2019**

The goal of the Improving Patient Safety system is to collect information about safety related incidents occurring system-wide, in order to increase organ utilization and decrease the morbidity and mortality of transplant patients.

What is a Safety Situation?
A situation or activity that affected or could have affected patient safety.

What to report:

- Any patient safety situation
- Any other situation that causes a safety concern from a transplantation, donation, and/or quality perspective.

Please report such situations in a timely manner.

Situation Information

Reporting Institution: ✳ [redacted]-Transplant Hospital(Member)

Type of Safety Event (Choose all categories and subcategories that are applicable): ✳

- ☐ Communication
- ☐ Data Entry
- ☐ Transportation
- ☐ Packaging/Shipping
- ☐ Labeling
- ☐ Recovery Procedure/Process
- ☐ Transplant Procedure/Process
- ☐ Testing
- ☑ Organ Allocation/Placement
  - ☐ Offer rescinded
  - ☐ Offer not made to secondary contact
  - ☐ Out of sequence allocation
  - ☑ Inaccurate patient priority or status
  - ☐ Recipient not on match run
  - ☐ Inaccurate donor data caused match to run incorrectly
  - ☐ Match not rerun once serology found to be positive
  - ☑ Other (please describe in the description field below)
- ☐ Other (please describe in description field below)

The Issue reported involves the following (choose all categories that are applicable): ✳

- ☑ **Recipient/Candidate**
  Waitlist ID: [redacted] **No Waitlist ID:** ☐
- ☐ **Donor Organ/Extra Vessels**
- ☐ **Other (please describe in the description field below)**

Date Event Occurred: ✳ 02/06/2019

Detailed Description of the Event: *

We received a heart-lung offer for patie [redacted] sequence 19 (heart) and 20 (heart-lung). All previous offers declined so we were primary. Notified by OPO lungs had already been placed. The OPO AOC was contacted by OPO on-site in an attempt to obtain rationale for the lung placement-none provided. OPO coded us out for 830 without our knowledge. We believe we should have been offered the lungs based on OPTN policy 6.6F.i. Additionally, the same situation occurred on 10/16/18 with the same OPO. UNOS ID AFJM361 match 1134453. Our recipient in this case did not survive to transplant The recipient was of small stature and this was one of the very few opportunities for a transplant. D[redacted]pulmonologist on -call, contacted the accepting physician in an attempt to get him to agree to release the lungs for this heart0-lung candidate, but he refused. Our physicians, D[redacted] (cardiologist) and D[redacted] (pulmonologist) were both involved with one or both of these offers.

Has a root cause analysis (RCA) been completed? * ○ Yes ◉ No ○ In Progress

Please specify additional details regarding the RCA: NA

Please upload any relevant attachments:

Contact Information

Who at your institution should UNOS contact about this case?

First Name: * [redacted] **Last Name:** * [redacted]

Phone contact (Enter at least one): *

Office: [redacted] **ext.** **Pager/beeper:** **ext.**

Mobile: [redacted] **ext.** **Other:** **ext.**

Email: * [redacted]

Other contact info:

UNOS Only

Reported by: [redacted]

Initial UNOS Action

Date: * 02/07/2019 **Staff member:** [redacted]

Status: * In process **Urgency:** * Low

Category: * Major

Potential policy violation: ○ YES ○ NO

Committee notification? ○ YES ○ NO

Type of Safety Event (Choose all categories and subcategories that are applicable):

- ☐ Communication
- ☐ Data Entry
- ☐ Transportation
- ☐ Packaging/Shipping
- ☐ Labeling
- ☐ Recovery Procedure/Process
- ☐ Transplant Procedure/Process
- ☐ Testing
- ☐ Organ Allocation/Placement
- ☐ Other (please describe in description field below)

Attachments

UNOS
UNITED NETWORK FOR ORGAN SHARING

Matching organs. Saving lives.

[redacted]

CONFIDENTIAL MEDICAL PEER REVIEW

February 13, 2019

VIA SECURE EMAIL

[redacted]

Dear [redacted]:

The United Network for Organ Sharing (UNOS) serves as the Organ Procurement and Transplantation Network (OPTN) under contract with the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services. Under that contract, UNOS staff review reported or identified patient safety and/or public health-related concerns associated with organ donation and transplantation occurring within the OPTN.

UNOS' Member Quality staff screen all reports to determine whether the matter suggests a risk or threat to patient safety or public health. Often additional information is needed from the involved OPTN member(s) to finalize the assessment of threat. If the matter is assessed as both time-sensitive and serious, this department will alert OPTN leadership and, under that direction, work with OPTN member(s) to alleviate the threat.

UNOS' Member Quality Department staff also screen all reports to determine if there is a possible violation of OPTN/UNOS bylaws or policies associated with the matter. Again, additional information is typically needed from OPTN member(s) involved in order to complete the assessment.

We are currently reviewing two lung allocations by [redacted]. First, our preliminary analysis indicates that on October 16, 2018, the heart from donor [redacted] was offered to PTR #41 on the heart/lung match, who also required lungs. The heart evaluating center requested the lungs, but [redacted] had already placed the lungs from the standalone lung match prior to making heart offers.

Second, on February 6, 2019, the heart from donor [redacted] was offered to PTR #19 and #20 (same patient) on the heart/lung match, who also required lungs. The heart evaluating center

[redacted]

requested the lungs, but [redacted] had already placed the lungs from the standalone lung match prior to making this heart offer.

We are contacting you to obtain a complete understanding of what occurred. We appreciate as much detail as you can provide. Any information you provide that suggests a potential policy or bylaw violation, or which may pose a threat to transplant or donor patient health or public safety may be referred for review by OPTN leadership, including the Membership and Professional Standards Committee (MPSC), and in some cases the OPTN Board of Directors.

Please address the following issues related to these allocations:

- For donor [redacted]:
  - Provide a detailed overview of the heart and lung allocations, including a timeline detailing when offers were made, provisionally accepted, and organs placed.
  - Detail and provide available documentation of all communications between [redacted] and evaluating heart centers who also requested the lungs.
  - Explain the decision to place the lungs from a standalone match run prior to offering the heart.

- For donor [redacted]
  - Provide a detailed overview and timeline of the heart and lung allocations, including when offers were made, provisionally accepted, and organs placed.
  - Detail and provide available documentation of all communication between [redacted] and evaluating heart centers who also requested the lungs.
  - Explain the decision to place lungs from a standalone match run prior to placing the heart.
  - The Donor Heart Study attachment states that the heart was declined for PTR #19 due to size. Who at the evaluating center declined this heart due to size? The document also indicates that the heart was declined for PTR #20 because the lungs were not available. Please explain why the reasons for decline are different for these PTRs.
  - Describe why [redacted] entered code 830 for PTR #19 and #20.

- Was a root cause analysis or post case review performed as a result of these allocations? Please provide the results, if available.

- Provide your policies and/or Standard Operating Procedures for offering a heart and lung from the same deceased donor. Were these protocols followed in this case? If not, please explain.

- Were any corrective actions developed as a result of this event? If so, include documentation that supports these corrective actions, such as revised policy, training materials, etc.

The OPTN bylaws and policies guide the sequence of allocation and wait listing practices of OPTN members in an effort to assure equitable organ allocation for transplant. The bylaws and

policies also guide safe and effective practice connected to organ transplantation and living donor care. UNOS is responsible for monitoring compliance by OPTN members with these OPTN obligations, as well as for processing reports of transplant-related patient safety and living donor safety.

The MPSC, and in certain cases, the OPTN Board of Directors, perform the peer review functions of the OPTN. Please be aware that this correspondence and all documents and information requested by UNOS staff, on behalf of the OPTN, are protected by applicable peer review statutes and will not be disclosed. For this reason, all associated reports, inquiries, deliberations, findings, recommendations, and actions must be kept confidential. This means we will not be able to provide you with the results of our investigation.

I look forward to hearing from you by **February 20, 2019**. Responses can be sent via mail, email and/or fax. I can be contacted at [redacted]@unos.org or fax [redacted]. Thank you in advance for providing the additional information requested.

Sincerely,

[redacted]
Safety Analyst
UNOS Member Quality

cc: [redacted] Director, UNOS Member Quality

CISCO

Secured Message

Reply ReplyAll Forward

From: [redacted]
To: [redacted]unos.org[redacted]
CC: [redacted]
Date: 02/13/2019 12:58:47 PM EST
Subject: RE: Secure: UNOS Request for Information [redacted] Donors [redacted] and [redacted]

Thank you [redacted]

----------Original Message:

From: [redacted]@unos.org
To: [redacted]
CC: [redacted]
[redacted]
Date: 02/13/2019 05:51:37 PM GMT
Subject: RE: Secure: UNOS Request for Information - [redacted] Donors AFJM361 and AGBE241

Hi [redacted]

Thank you for your response. I look forward to receiving your full response to the inquiry. I discussed with [redacted] the need for a few more days to this, and an extension to next Friday, February 22, is absolutely fine.

Sincerely,
[redacted]

----------Original Message:

From: [redacted]
To: [redacted] &[redacted]
[redacted]
Date: 02/13/2019 12:22:04 PM EST
Subject: RE: Secure: UNOS Request for Information - [redacted] - Donors [redacted] and [redacted]

Dear [redacted]

I am confirming receipt of this inquiry. We are assembling necessary documentation that clearly shows we were 100% compliant with policy. The

complaining center is not taking into account the fact that over the course of the allocation, accepted organs were subsequently declined, leaving other organs already placed. There were zero efforts to avoid policy requirements or to avoid placement of available organs to this center or any centers.

Our documentation is forthcoming. We will supply what is necessary to clearly substantiate my description above but will not supply additional

information that seems to be requested from a position by the complaining center of assuming ill will or intentional or accidental avoidance of allocation policy, such as logs or recordings of all communications.

Respectfully,

[redacted]

----------Original Message:

From: [redacted]@unos.org>
To [redacted]
CC [redacted]
Date: 02/13/2019 04:12:57 PM GMT
Subject: Secure: UNOS Request for Information [redacted] - Donors [redacted] and [redacted]

Please find the attached correspondence in reference to Donor IDs [redacted] and [redacted] If you have any questions, feel free to contact me at [redacted] (link: [redacted]

Reply ReplyAll Forward

[redacted]

From: [redacted]
Sent: Wednesday, February 20, 2019 4:02 PM
To: [redacted]
Subject: Response from [redacted] re: H/L allocation questions
Attachments: UNOS Response Letter [redacted] and [redacted] Final.docx; PO69.pdf

[redacted]
Please see attached.

Sincerely,

[redacted]
Director Quality Systems

[redacted]

[redacted]

February 20, 2019

[redacted]
Safety Analyst
UNOS Member Quality

Dear [redacted]

Please find the response to the UNOS lung allocation inquiry dated February 15, 2019 regarding lung allocation for donor UNOS ID [redacted] and [redacted]

Please address the following issues related to these allocations:

- For donor [redacted]
  - *Provide a detailed overview of the heart and lung allocations, including a timeline detailing when offers were made, provisionally accepted, and organs placed.*
    - 10/15/18 -Lungs accepted by [redacted] for sequence #3
    - 10/15/18@17:54 The heart was accepted by [redacted] for sequence #1
      - Heart allocation was delayed due to donor pressor requirements. In order to have the best chance for the heart to be utilized it was decided to continue to give the donor time to stabilize hemodynamically and obtain an echo when pressor requirements were lower and heart function was optimized.
      - Lung allocation was started prior to echo being obtained.
    - 10/15/18 @ 20:13 [redacted] declined the heart
    - 10/15/18 @20:15 [redacted] continued with heart allocation
    - 10/16/18 12:14 [redacted] entered a provisional acceptance for sequence #41- 19 hours after initial heart offer was made.
      - [redacted] inquired about the lungs and was advised the lungs were allocated and accepted the day before prior to the heart being declined by the original accepting center
      - [redacted] asked if it would be possible for us to contact the accepting lung center asking to release lungs to their center. [redacted] advised [redacted] this will be in violation of OPTN policy, [redacted] mentioned they will contact [redacted] and inquire about the lungs. Unknown whether contact was made.
      - After numerous conversations with the team at [redacted] that we would not rescind the lungs that had already been allocated they eventually declined the offer.
        - Heart accepted by [redacted]
  - *Detail and provide available documentation of all communications between [redacted] and evaluating heart centers who also requested the lungs.*
    - Refer to [redacted] earlier email
  - *Explain the decision to place the lungs from a standalone match run prior to offering the heart*

[redacted]

- The donor remained on a substantial dose of levophed and the decision was made with Chief Medical Officer and the AOC to continue to allow the heart to recover prior to obtaining an echo.
- Given the high pressor requirements for this donor and that all heart recipients status 1 and status 2 in zone A did not require lungs, the decision was made to begin lung allocation.

For donor [redacted]

- *Provide a detailed overview and timeline of the heart and lung allocations, including when offers were made, provisionally accepted, and organs placed.*
  - 2/5/19@21:18 [redacted] accepted the heart for sequence # 5
  - 2/5/19@22:37 [redacted] accepted for a combined lung/kidney for sequence # 2 LAS: 64.699
  - 2/6/19@06:20 [redacted] declined the heart. Reallocation of heart began on 2/6/19 at 0820
  - 2/6/19 09:47 [redacted] given primary offer for sequences #19-20
    - [redacted] inquired about the lungs and were advised that lungs were previously accepted prior to the heart being declined by the primary center.
    - [redacted] asked for us to contact the accepting lung center to see if they would decline the lung offer for them to be able to accept it for sequence #20. [redacted] was informed this was a violation of OPTN policy. [redacted] later informed they will contact [redacted] regarding the lung offer.
    - [redacted] later told the [redacted] coordinator that they would be declining and coding out for their center.
    - Numerous attempts were made by the [redacted] via phone call and text message to contact [redacted] for them to enter their refusal code without response.
    - In order to proceed with allocation and six hours after the offer to [redacted] entered a refusal code for the center. Additionally, there was a 48-hour time constraint placed on donation by the family. [redacted] was not able to place the heart for transplant and feel these unnecessary delays led to organ wastage.

- *Detail and provide available documentation of all communication between [redacted] and evaluating heart centers who also requested the lungs.*
  - See [redacted] prior email

- *Explain the decision to place lungs from a standalone match run prior to placing the heart.*
  - The heart was allocated and accepted prior to lung allocation, see above details.

- *The Donor Heart Study attachment states that the heart was declined for PTR #19 due to size. Who at the evaluating center declined this heart due to size? The document also indicates that the heart was declined for PTR #20 because the lungs were not available. Please explain why the reasons for decline are different for these PTRs.*
  - During initial contact with [redacted] coordinator, [redacted], she verbally provided the decline reasons as noted on Heart Study worksheet.

[redacted]

- Attempts were made to recontact [redacted] to ask that they enter PTR refusals, [redacted] did not receive a response so code 830 was entered to allow progression of allocation, since the prior codes were not able to be confirmed.

- *Describe why [redacted] entered code 830 for PTR #19 and #20.*
  - See above details for explanation regarding [redacted] entering the refusal codes for [redacted].

- *Was a root cause analysis or post care review performed as a result of these allocations?*
  - Neither an RCA or post case review performed

- *Provide your policies and/or Standard Operating Procedures for offering heart and lung from same deceased donor. Were those protocols followed in this case? If not, explain why not.*
  - OPTN policy for Heart lung allocation was followed.
  - Attached is current [redacted] policy.
  - OPTN allocation policy takes precedence of OPO policy.

- *Were corrective actions developed as a result of this event? If so, include documentation that supports these corrective actions, such as revised policy, training materials, etc.*
  - Instructions have been given to placement staff that if a center refuses to provide or confirm refusal codes, they will be entered as 898 and specify that center refused

Please feel free to contact [redacted] if you have further questions.

Sincerely,

[redacted]
Director Quality Systems

Cc:
[redacted], CEO
[redacted], Vice President Organ Operations
[redacted] Vice President and Chief Medical Officer

[redacted]

[redacted] Standard Operating Procedure

Number	PO69	Revision	.003	Effective	October 7, 2015
Title	Multi-Organ Allocation				
Supersedes	PO69.002 (Effective February 12, 2015)				

1.0 Purpose:

1.1 To assure equitable allocation of donated organs by:

1.1.1 Providing a policy for staff in making offers on multiple organ lists when candidates requiring more than one organ appear on the organ match run.

1.1.2 Ensuring that organs are allocated only to those recipients that appear on the particular match run for that donor organ.

1.1.3 Ensuring that match runs with Status 1 hearts and Status 1A livers receive organ offers prior to match runs without such patients on the list.

1.2 Organ allocation will be accomplished in such a manner as to maximize organs recovered from every donor and to minimize organs lost due to donor instability, organ function, or discards.

1.3 Donated organs shall be allocated according to current OPTN standards.

2.0 Scope:

2.1 This procedure applies to all Organ Recovery Staff

3.0 System Owner:

3.1 Organ Recovery

4.0 Approvers:

4.1 Managing Director of Clinical Operations

4.2 Chief Medical Officer

4.3 Director of Quality Systems

5.0 Responsibilities:

5.1 All Organ Procurement personnel are responsible for understanding and complying with this procedure.

6.0 Definitions:

6.1 NA

7.0 Referenced Documents:

7.1 PO06 Kidney Allocation

7.2 UNOS Policy 2 Deceased Donor Organ Procurement

7.3 UNOS Policy 6 Allocation of Heart and Heart-Lungs

7.4 UNOS Policy 9 Allocation of Livers and Liver-Intestines

8.0 Forms and Attachments:

8.1 NA

9.0 Procedure:

9.1 Match Runs will be reviewed by AOC and DCS/DRS for all donors within the [redacted] Donor Service Area.

9.1.1 Each match run initiated for the specific donor will be reviewed by the AOC and the DCS prior to the initiation of offers from that specific match run.

9.1.1.1 During review of the Match Runs, candidates requiring a multi organ transplant will be identified.

9.1.1.2 **For combined Heart/Lung:**

9.1.1.2.1 [redacted] will follow OPTN Policy 6, as stated:

6.5.E Allocation of Heart-Lungs. When a heart-lung candidate is allocated a heart, the lung from the same deceased donor must be allocated to the heart-lung candidate. When the heart-lung candidate is allocated a lung, the heart from the same deceased donor may only be allocated to the heart-lung candidate if no suitable Status 1A isolated heart candidates are eligible to receive the heart. The blood type matching requirements described in *Policy 6.5.A: Allocation of Hearts by Blood Type* apply to heart-lung candidates when the candidates appear on the heart match run. The blood type matching requirements in *Policy 10.4.B: Allocation of Lungs by Blood Type* applies to heart-lung candidates when the candidates appear on the lung match run.

9.1.1.3 **For combined Liver-Intestine:**

9.1.1.3.1 [redacted] will follow OPTN Policy 9, as stated:

Refer to OPTN Policies, **9.6.H Allocation of Liver-Intestine from Donors at Least 18 Years of age** and **9.6.I Allocation of Liver-Intestine from Donors less than 11 Years of age** for specific allocation tables

9.6.J Allocation of Liver-Intestine from Donors at Least 11 Years of age. For combined liver-intestine allocation, from donors at least 11 years of age, the liver must first be offered:
• according to *Policy 9.6.F: Allocation of Livers from Deceased Donors 11 to 17 Years Old*
• sequentially to **each** potential liver recipient including all MELD/PELD potential recipients through national Status 1A and 1B offers.

The liver may then be offered to combined liver-intestine potential recipients sequentially according to the intestine match run.

9.1.1.4 **For combined Kidney/Pancreas:**

9.1.1.4.1 Refer to [redacted] Policy PO06 'Kidney Allocation'

9.2 **For other Multi-Organ combinations not specified above:**

9.2.1 [redacted] will follow OPTN Policy 5.8, as stated:

5.8.B Other Multi-Organ Combinations. When multi-organ candidates are registered on the heart, lung, or liver waiting list, the second required organ will be allocated to the multi-organ candidate from the same donor if the donor's DSA is the same DSA where the multi-organ candidate is registered. If the multi-organ candidate is on a waiting list outside the donor's DSA, it is permissible to allocate the second organ to the multi-organ candidate receiving the first organ.

9.3 Local Conflicts:

9.3.1 Should a conflict in allocation of organs arise, the AOC will notify the Medical Director and Director of Quality Systems. Resolution will be at the discretion of the Medical Director and/or the Director of Quality Systems with input from the transplant centers involved.

Number	PO69	Revision	.003	Effective	OCTOBER 7, 2015
Title	MULTI-ORGAN ALLOCATION				
Supersedes	PO69.002 (EFFECTIVE FEBRUARY 12, 2015)				

Document Revision History

Contact Document Control for information regarding previous revision levels.

Revised By	Effective Date	CCO	Rev	Summary of Changes
[redacted]	02/12/2015	CC-15-001	.002	• Updated format and OPTN references
[redacted]	10/07/2015	CC-15-015	.003	• Section 1.3 removed references to variances • Updated UNOS to OPTN and updated policy numbers • Section 9.1.1.3.1 removed outdated OPTN policy • Section 9.2.1 updated to reflect current OPTN policy

[redacted]

From: [redacted]
Sent: Wednesday, February 27, 2019 12:19 PM
To: [redacted]
Cc: [redacted]
Subject: FW: Response from [redacted] re: H/L allocation questions
Attachments: AGBE241 allocation note.docx; AllocationNotes (6).pdf

[redacted]

Please see below.
Also attached is the only documentation found to be generated. There are not recorded conversations.

Sincerely,

[redacted]
Director Quality Systems

[redacted]

Regarding our response that [redacted] accepted at 2118 they were actually given the offer at 2118 and placed a provisional yes at 2125 so that was an error in our response letter. [redacted] called [redacted] coordinator and informed them they were a provisional yes pending a crossmatch (see attached case notes). [redacted] backed up the heart and had provisional acceptance at sequence number 6&7. [redacted] declined due to positive crossmatch at 0725. Sequence 6&7 were then given primary offers and subsequently declined. [redacted] began to allocate the heart and had interest in the heart at sequence number 12 with a request for a cardiac cath. [redacted] continued to allocate for a backup throughout the process and during the time that [redacted] had the primary offer with provisional acceptances pending primary offers.

We have attached documentation from allocation however the decision to not rescind the primary lung offer from the accepting center was a discussion between the AOC, the VP of Organ Operations, and [redacted] CMO and was not captured in documentation. We would like to reiterate that we had provisional acceptance for the heart in classifications that require heart allocation before heart lung allocation therefore the lungs were allocated from the lung PTR. Delaying lung allocation for potential heart lung candidates that are in Zone B would have caused unnecessary delays in this case.

[redacted]

Vice President Organ Operations

[redacted]

From: [redacted]
Sent: Monday, February 25, 2019 4:53 PM
To: [redacted]
Subject: RE: Response from LifeGift re: H/L allocation questions

Ok

We need to make sure they are not trying to go after [redacted] and it looks like they only need info on 1 of the cases. Re communications, not sending recordings or stuff that is tangential unless absolutely necessary. This is still in allocation analysis it seems.

Thx

[redacted]

President & Chief Executive Officer

[redacted]

[redacted]

From: [redacted]
Sent: Monday, February 25, 2019 3:54 PM
To: [redacted]
Subject: Fwd: Response from [redacted] re: H/L allocation questions

Request for more info,

Get Outlook for Android

From: [redacted]:@unos.org>
Sent: Monday, February 25, 2019 3:31:45 PM
To: [redacted]
Subject: RE: Response from [redacted] re: H/L allocation questions

[redacted]

Thank you for your response to my inquiry regarding donors [redacted] and [redacted]. I need some additional information regarding the heart allocation for donor [redacted] that I'm hoping you can provide.

1. Your response states that [redacted] accepted the heart on 2/5/19 at 21:18 for PTR #5. The Offer History shows only [redacted]'s Provisional Yes at 21:25 and Decline Code of 810 (Positive Crossmatch) on 2/6/19 at 07:25. Was the acceptance conveyed to [redacted] via a different format (i.e., text message, phone call)? If so, please provide documentation of that acceptance and explain why there was not an Acceptance immediately entered into DonorNet for this offer. Was [redacted]'s acceptance reported to the OPTN Contractor via a different format? If so, please provide documentation of that report.
2. Did [redacted] communicate to [redacted] that a crossmatch was required and/or that their acceptance was provisional pending crossmatch? If so, when did they communicate this to [redacted] and did [redacted] make any back-up offers as a result?
3. Your response states that [redacted] staff proceeded with allocation six hours after the offer to PTR #19 and #20 at [redacted]. Please describe why [redacted] did not begin actively pursuing offers to the next transplant center(s) and/or arranging back-up offers sooner than six hours after the offer was made to [redacted].

In [redacted]'s email on February 13, 2019, he stated that [redacted] would not be providing documentation of communication. As we review this case for possible review by the MPSC, that documentation could be helpful in clarifying the events of these allocations because timelines and activities are not clear in DonorNet for donor AGBE241. If you think it would help highlight or explain [redacted]'s efforts during these allocations, I would encourage you to send them.

A response by **Wednesday, February 27, 2019**, is appreciated. Please feel free contact me if you have any questions.

Sincerely,

[redacted], M.P.A.
Safety Analyst

Patient Name: [redacted]
ABO: O

UNOS #: AGBE241
OPO #: [redacted]

[redacted]

ALLOCATION NOTES

Heart
[redacted]
02/07/2019 00:26
Late note: Heart was originally accepted by [redacted]. Heart team had transportation issues. Declined heart. Allocated up until OR at 2000. Heart was not placed. Per DCS [redacted] heart allocation ceased and heart will not be going for tx.

Heart
[redacted]
02/06/2019 09:09
seq 12 [redacted] requested cath, cmo agreed

Heart
[redacted]
02/06/2019 07:35
0620: Received a text from [redacted], TC, [redacted] that [redacted] is declining this heart offer for postive xm's.

0628: Notified [redacted] that their center is primary for this heart offer. Received a call back from [redacted]. Confirmed heart offer. She will review.

Heart
[redacted]
02/06/2019 05:13
Recieved a text from [redacted]. She stated that she touched base with HLA labe. XM should result by 0700. [redacted] will be taking over for her at 0630.

Heart
[redacted]
02/06/2019 00:10
[redacted], TC [redacted], is provisionally accepting heart for seq #5 pending xm which should be resulted ~0400.

Heart
[redacted]
02/05/2019 22:49
[redacted] [redacted] virtual xmatch for seq#5 requesting xmatch blood, was updated blood has been picked up

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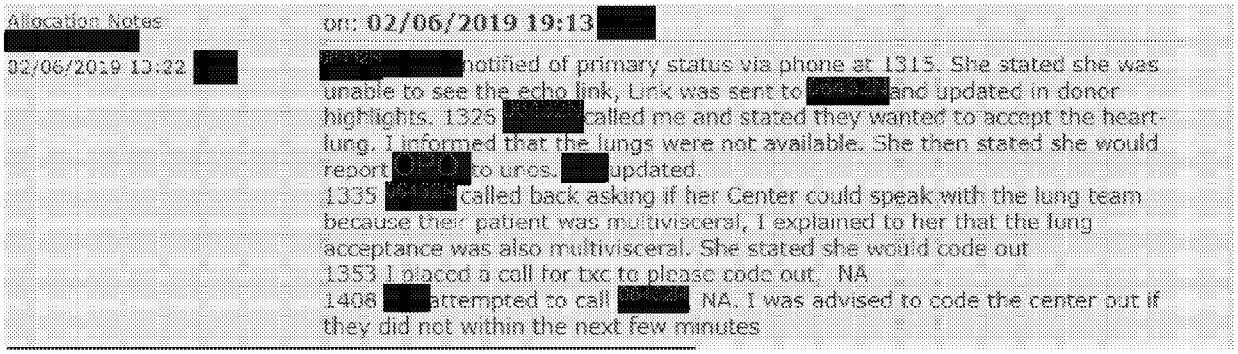

Allocation Notes [redacted]

on: **02/06/2019 19:13** [redacted]

02/06/2019 13:22 [redacted]

[redacted] notified of primary status via phone at 1315. She stated she was unable to see the echo link, Link was sent to [redacted] and updated in donor highlights. 1325 [redacted] called me and stated they wanted to accept the heart-lung. I informed that the lungs were not available. She then stated she would report [redacted] to uros. [redacted] updated.
1335 [redacted] called back asking if her Center could speak with the lung team because their patient was multivisceral, I explained to her that the lung acceptance was also multivisceral. She stated she would code out
1353 I placed a call for txc to please code out. NA
1406 [redacted] attempted to call [redacted] NA. I was advised to code the center out if they did not within the next few minutes