OPTN Heart Transplantation Committee
Meeting Summary
October 11, 2022
Chicago, Illinois

Rocky Daly, MD, Chair
JD Menteer, MD, Vice Chair

Introduction

The OPTN Heart Transplantation Committee met in Chicago, Illinois on 10/11/2022 to discuss the following agenda items:

1. Presentation of findings from 3-Year Monitoring Report for 2018 Modifications to Adult Heart Allocation Policy, the 2-Year Monitoring Report for the changes implemented as a result of the Eliminate the Use of DSA in Thoracic Distribution project, and member questions
2. Committee work: Members indicate and discuss potential attributes for Heart Continuous Distribution
3. Committee work: Assign smalls groups to research the potential attributes identified and schedule reporting of findings back to Committee
4. Committee work: Review recommendations Proposed in National Academy of Science, Engineering, and Medicine (NASEM) Report: Realizing the Promise of Equity in the Organ Transplantation System (2022) and Committee Feedback
5. Action item: Review public comment feedback received for Modify Heart Policy to Address Patient Safety Following Device Recall emergency policy and Committee vote to recommend that Board make policy permanent
6. Action item: Review of proposed policy changes associated with Modify Heart Policy for Pediatric Candidates and Intended Blood Group Incompatible (ABOi) Offers and Committee vote to submit proposal for public comment
7. Committee work: Educational email topics
8. Open Discussion and Closing Remarks

The following is a summary of the Committee's discussions.

1. Presentation of findings from 3-Year Monitoring Report for 2018 Modifications to Adult Heart Allocation Policy, the 2-Year Monitoring Report for the changes implemented as a result of the Eliminate the Use of DSA in Thoracic Distribution project, and member questions

UNOS Research staff presented the findings from the 3-Year Monitoring Report for the 2018 Modifications to Adult Heart Allocation policy and the 2-Year Monitoring Report from the Eliminate the Use of DSA in Thoracic Distribution project. This presentation compares outcomes between the previous allocation policy with the current heart allocation policy. The Committee considered the report findings and discussed how it could be used to revise the current Status 2 policy requirements with specific regard to the Intra-Aortic Balloon Pump (IABP) criterion.

The Committee also received a presentation about the findings associated with the 2-year Monitoring Report for Eliminate the Use of DSA in Thoracic Distribution. The monitoring report reviewed the impact of policy changes implemented on 01/09/2020, by comparing a pre-policy change period (01/08/2019-

01/08/2020) to a post-policy change period (01/09/2020-01/09/2022). Highlights from the report include: hearts are traveling slightly farther and the overall transplant rate increased post-policy, without negatively impacting total ischemic time, waiting list mortality, organ utilization, or one-year post-transplant survival.

Data summary:

The full report can be found on the OPTN website and the Committee's Sharepoint site.

Summary of discussion:

Discussion of Status 2 IABP Findings

The Committee members discussed how to ensure that the medical urgency between Status 2 and Status 3 patients are accurately reflected in their status assignment and placement on the waitlist. Currently, when reviewing 'Deaths per 100 Patient-Years Waiting by Criteria within Medical Urgency Status,' status 2 patients with an IABP more closely align with Status 3 criteria patients than status 2 criteria patients. A member inquired about length of stay and morbidity data to provide a more holistic understanding of the medical urgency of IABP patients. A member suggested requiring centers to provide the patient's cardiac index and hemodynamics while on a device in order to tease out the level of support that a patient is receiving from a given device. Members noted the responsiveness of the heart community and were conscientious of how program behaviors may change as policy changes.

A member cautioned against showing favoritism between devices in policy as it could increase the overuse of another device, while another member pushed back on the cost break down between devices which may already be leading to favoritism. Members did not want to discourage programs from using devices that are the most appropriate for a given patient and requested a breakdown of IABP use by gender to ensure there was adverse use or potential negative impact between genders if modified. However, members suggested that the current policy disadvantages patients with left ventricular assist devices (LVAD) and priority could be added to those candidates based on their wait time on the device. Members suggested that providing additional waiting time for LVAD would be a long term solution that could be implemented with continuous distribution.

The group noted that the goal of the policy, or any policy modification, is not to gatekeep any certain status from patients but to instead spread patients out across statuses that most accurately reflect their medical urgency. The Committee feels that there should not be a concern that status 4 patients on an LVAD are unlikely to be transplanted, but that all patients across statuses are able to be transplanted when appropriate.

A member commented that the statuses may better serve patients if they were more dynamic and responsive to changes in patient stability, which could occur if it was required that current clinical data must be reported to warrant an extension. Members discussed alternatives to automatic extensions and whether only one extension would be appropriate. A member pushed back that this could disadvantage patients in rural populations who have a smaller organ pool and may be on the waitlist longer despite their medical urgency. A member was concerned that additional exctentions could be available but would require a higher threshold of supporting data and not occur automatically. However, there was some level of concern about limiting a center's autonomy to determine what treatment type they believe to be the best fit for their patient.

Members discussed the role of exceptions and shared anecdotal experiences of centers submitting status 2 exceptions for an IABP despite any prior attempt to modify treatment gradually from status 4 to status 3. A member suggested a stronger accountability tool in the exception process overall. A member praised the previous regional review board (RRB) system of having video calls for each exception request

and opined that the anonymity of the current system falls short of holding people accountable. A member voiced support for a more accountable and reprimanding system when exceptions are continually denied and patients are transplanted at a denied status. The member proposed a threshold for denied exception requests leading to a limitation of future exceptions in order to hold centers more accountable in their practices. Members suggested looking into the data about exceptions and rates of programs transplanting patients at a denied status. Members considered developing 'report cards' that reflect RRB practices compared to their region and other regions.

A member suggested providing a directive to RRBs that if certain information is missing from the exception request they must deny the request. However, a member responded that as an autonomous review body they have the authority to accept or deny an exception request and not to be influenced. A member suggested informing and empowering review boards to deny appeals. The Chair noted that it's the responsibility of the RRBs to uphold policy and denying exception requests ought to be standard, especially if the request does not align with the policy guidance.

The goal of this potential new project would be an short term solution while the Committee develops the continuous distribution allocation framework. While this modification would be implemented prior to continuous distribution, it needs to align with the Committee's goals of continuous distribution and mesh with the new framework. Ultimately, the Committee came to a consensus on three areas they may be interested in developing policy:

- Mandatory hemodynamics prior to temporary support
- Term limits for exception requests
- Additional benefits for patients on VAD to reflect their waiting time

Next steps:

UNOS Staff will follow up with IT and Research to gain a better understanding of what resources would be needed to pursue the three options that the Committee identified. The Committee will continue to discuss these options in future meetings.

2. Committee work: Members indicate and discuss potential attributes for Heart Continuous Distribution

The Committee began discussing the potential attributes for consideration into the heart continuous distribution framework. Attributes are criteria or factors to classify then sort and prioritize candidates. The attributes will be combined to develop a composite allocation score (CAS). There are five overarching goals that each attribute will align with: medical urgency, post-transplant survival, candidate biology, patient access, and placement efficiency.

The goals were written on large pieces of paper around the room and members shared what new attributes they think are the most important for each goal. Once the lists were finalized, members were given sticky notes and asked to vote for five new attributes they think the Committee should prioritize in continuous distribution.

Summary of discussion:

Medical Urgency

The Committee acknowledged that statuses were already in heart allocation policy, but felt confident that the statuses would persist in the continuous distribution framework. Members agreed that time on VADs and VAD complication should be included.

The attribute for members to vote onwas: Time on VAD and VAD complications. Adult statuses 1-6, pediatric statuses 1A, 1B, 2, and types of devices were identified as already being in policy.

Post-Transplant Survival

Members emphasized that current policy does not consider post-transplant survival. The Commtittee was assured that while this goal has been identified for all organs, the Committee does not need to include attributes in post-transplant survival for their first iteration of continuous distribution. Alternatively, they do have the option to add new data collection that could inform a future post-transplant survival score. 'Re-transplant' was identified because patients receiving a second heart transplant do not tend to do as well post-transplant.

Members identified 'pre-sensitization,' 'complex congenital heart disease (CHD),' 're-transplant,' and 'primary graft dysfunction' as contributors to post-transplant survival and were attributes that members could vote on.

Candidate Biology

A member distinguished that candidate biology ought to be factors of the patient that are unable to be changed and impact their clinical presentation and acceptable organs in some capacity. Members suggested 'blood type' and 'CPRA sensitization.' Members questioned whether CPRA should be grouped with candidate biology or patient access. The Committee opted to put CPRA under both goals for the time being. 'Frailty,' 'candidate size matching,' and 'congenital heart disease' were added to the list. Members discussed 'functional status' and whether or not that should be included, and if so, if it should be in candidate biology or medical urgency. 'Functional status' could be reflected by the 6 minute-walk test. A member commented that this may not be the most representative test to use, but a member pushed back that this is the data programs have available.

Candidate age was identified as an attribute. A member suggested a sliding-scale of points based on age since older age can be a risk factor for complications post-transplant. A member inquired if they would use attributes to deduct points, but were advised to provide points where necessary as opposed to deducting points. The Chair noted the ethical principle of innings played that would support the inclusion of this attribute. A member suggested incuding 'patient disability' to reflect physical and intellectual disabilities.

The attributes for members to vote on were: re-transplant, HLA sensitization, frailty, size-matching, donor-recipient age, CHD, and patient disability. Blood type was identified as already existing in policy.

Patient Access

Socioeconomic factors and access to the waitlist were considered as attributes for patient access. These characteristics are being considered by the OPTN Liver and Intestine Transplantation Committee for inclusion in their continuous distribution framework. Based on this discussions it seems unlikely that this information could be included in the first iteration of continuous distribution of hearts due to the level of complexity and necessity for additional information.

Size matching was considered for candidate biology, but the Committee was advised to list it under patient access instead. The Committee also listed CPRA in patient access because it impacts the pool of organs they have access to. 'Prior living donors' have been identified as an attribute that ought to be included across all organs in patient access. The group listed 'multi-organ' under patient access. The Committee considered if 'population density' would fit under placement efficiency, but decided that patient access was the appropriate goal. A member suggested including wait time in patient access to provide more points for patients had some disparity in access that limited to their access to the

transplant waitlist. The group agreed on using wait time on devices in medical urgency, but felt doubtful that considering wait time to address disparities in accessing transplant would be included in the first iteration of continuous distribtuon of hearts.

The attributes for members to vote on were: population density, CPRA, socioeconomic factors, size-matching, and multi-organ. Waiting time, prior living donor, and pediatrics were identified as already being in policy.

Placement Efficiency

'Distance' was suggested for inclusion, which is already a component of heart policy. Members considered various ways that distance could play a role, however, the determination of rating scales will be addressed after the final analysis and list of attributes. A litany of resources will be provided to the Committee to develop these rating scales and see how they appear in the simulation modeling. A member suggested including 'prospective cross matching' in placement efficiency because the need for this testing impacts the efficiency of placement and a center's ability to accept an organ offer.

The only placement efficiency attribute to vote on was prospective cross matching. Distance was identified as already existing in policy.

Donor Characteristics

The Committee opted to add a sixth category titled 'Donor Characteristics.' Donor age, whether they are a pediatric or adult donor, is a characteristic the group felt was important to consider, however, this is something that is already in policy. The Committee also added if a candidate was willing to accept a heart from a donor who has died by cardiac criteria (DCD). For those patients, the Committee wanted to include 'Perfusion Method' and identified between 'Normothermic Regional Perfusion (NRP)' and 'Organ Care System (OCS).'

The attributes for members to vote on where DCD and perfusion. Age was identified as already being in policy.

3. **<u>Committee work:</u> Assign smalls groups to research the potential attributes identified and schedule reporting of findings back to Committee**

Support staff shared the results of the member's votes on each attribute, highlighting which had the most support across each category.

<u>Summary of data:</u>

Attribute	**Votes**	**Attribute**	**Votes**
HLA Sensitzation/CPRA	15	Time on VAD	14
Size Matching	11	CPRA	7
Population Density	7	Prospective Cross Matching	7
Socioecomonic	6	Congenital Heart Diseases	5
Re-transplant	5	DCD	4
Patient disability	1	VAD Complications	1

Attribute	Votes	Attribute	Votes
Frailty	1	Multi-Organ	0
Perfusion: OCS vs NRP	0	Complex Congenital Heart Disease	0
Primary Graft Dysfunction	0	Pre-sensitization	0

Summary of discussion:

The Committee grouped the votes for HLA Sensitization and CPRA between patient access and candidate biology together and opted to categorize this attribute as aligning with the candidate biology goal. A member commented that the development of a post-transplant survival score would be very complex and challenging. A member suggested that a small group review the literature about risk factors and post-transplant survival and present that information to the Committee so they can add that data collection into continuous distribution to develop a future version post-transplant survival score.

The group realized that due to the where the 'age' was on the sheets placed around the conference room, the majority of the Committee missed it and did not vote for it. They felt it was an important attribute to consider and would like to develop a small group to look into this attribute.

Next Steps:

Members were asked to volunteer for small groups to research the potential attributes and report back to the full Committee with recommendations for consideration. The attributes available to sign up for are: time on VAD, size matching, CPRA/Sensitization, age, population density, and socioeconomic. Staff will send out the list of attributes for members to sign up for.

4. Committee work: Review recommendations Proposed in National Academy of Science, Engineering, and Medicine (NASEM) Report: Realizing the Promise of Equity in the Organ Transplantation System (2022) and Committee Feedback

Support staff reviewed the recommendations directed towards the OPTN as proposed in the National Academy of Science, Engineering, and Medicine (NASEM) Report: Realizing the Promise of Equity in the Organ Transplantation System. The review highlighted what efforts the OPTN is currently undertaking in alignment with these recommendations and asked members for feedback about projects the Heart Committee, or other OPTN Committees, could take up to address these recomendations.

Summary of discussion:

A member noted the gap in responsibility for ensuring access to transplant and the waitlist and considered if this gap should be closed by each organ-specific committee or by a Board level resolution. A member highlighted the difference between heart patients and kidney patients, wherein the Centers for Medicare and Medicaid Services (CMS) has oversight over dialysis centers. Additionally, there is extensive data about patients with kidney disease from the United States Renal Data System (USRDS), but there is no comparable dataset for patients with heart disease. From the program perspective, a member shared that their responsibility is to remove barriers once they are referred but noted the importance of referring providers to understand the process and shepherd the patients to the transplant center.

The Chair added that kidney patients have dialysis time, which carries a lot of weight in kidney allocation, whereas wait time in heart allocation has a much smaller impact. Given the complexity of heart patients, the Chair suggested providing additional benefit to patients who are supported by a VAD,

however, this does not resolve the issue of accessing transplant. A member suggested considering patients who were determined to be destination VAD but eventually end up needing a heart transplant down the line to receive some type of benefit, or points in continuous distribution, to include their previous time with VAD support. This could be a bridge to candidacy for some patients who were previously unable to access transplant. A member suggested that VADs may also be seen as a more cost effective option when compared to transplant.

Members discussed the importance of early referral for transplant in order for the transplant team to manage care in a way that will set the patient up for the eventual transplant, but identified a variety of challenges that limit this. First, there are guidelines that exist for when patients ought to be referred for transplant which would need to be revised to promote earlier referral. Second, a member suggested that providers are paid each time they see a patient so there is a financial disincentive for providers to refer patients earlier and remove them from their caseload. Lastly, providing telemedicine services could allow patients to access transplant providers earlier in the process. However, a member countered that increasing patient referrals would lead to an unsustainable volume of transplant referrals that programs would be unable to keep up with. Members suggested that metrics, penalties, or financial incentives were the best options to promote change in referral practices.

5. <u>Action item:</u> Review public comment feedback received for Modify Heart Policy to Address Patient Safety Following Device Recall emergency policy and Committee vote to recommend that Board make policy permanent

The Committee reviewed the Modify Heart Policy to Address Patient Safety Following Device Recall emergency policy that the Executive Committee approved and was implemented in July 2022. The proposal subsequently went out for retrospective public comment. As an emergency policy, it is only enacted for 12 months unless the Committee elects to submit the proposal to the Board of Directors to become a permanent policy.

The overarching themes from public comment were support for the policy, support for making the policy permanent, and some feedback on extending thetimeframes of the status assignments. The Committee reviewed the public comment feedback, discussed if modifications should be made, and voted to send the policy to the Board of Directors.

<u>Summary of discussion:</u>

The Committee discussed potential ways this policy could be modified in future iterations. A member suggested revising the 14 day time frame for re-application to a permanent status exception once the regional review board (RRB) approved the exception request. Member also suggested tiers eligibility criteria for each status. For example, a patient who remained outpatient should be granted a Status 3, a patient who required hospitalization should be granted a Status 2, and the patients who regularly had device failures be listed at Status 1. However, at this time there is not sufficient data to inform this decision, and would not be a warranted modification at this time.

There was a motion and a second to call the vote. The Committee was asked ‘Do you support sending the proposal to the Board of Directors for approval?’ There was unanimous support to send the proposal to the Board of Directors with 19 votes in support.

<u>Next steps:</u>

The proposal will move forward to the OPTN Board of Directors for their approval during the December Board meeting.

6. **<u>Action item:</u> Review of proposed policy changes associated with Modify Heart Policy for Pediatric Candidates and Intended Blood Group Incompatible (ABOi) Offers and Committee vote to submit proposal for public comment**

The Vice Chair reviewed the existing policy for pediatric candidates with intended incompatible blood type match (ABOi) offers and the background that identifies the necessity for a modification to the policy. A workgroup, comprised of members of the OPTN Heart and Pediatric Transplantation Committees, considered possible modifications and developed the proposed policy. The Vice Chair highlighted the various iterations this policy underwent in its development. Today, the Committee voted on whether to move this proposal forward for public comment, which would occur from January through March 2023.

<u>Summary of discussion:</u>

The Committee did not have any questions or suggestions for modification. There was a motion and a second to call the vote. The Committee was asked 'Do you support sending the proposal to the Board of Directors for approval?' There was support to send the proposal to the Board of Directors with 17 votes in support and 2 abstentions. The members who abstained noted that as adult only providers they did not feel they had the clinical expertise to weigh in on the discussion.

7. **Committee work: Educational email topics**

The Committee has two ideas for the educational emails. First, a clarification of the device recall policy (discussed above) indicating that this pathway is only available for patients with an implanted device that has been recalled by the FDA. Second, a notification to the heart community about the upcoming implementation of the Amend Status Extension Requirements policy. Due to the limited time remaining, staff will follow up with members about the educational emils via email.

8. **Open discussion and closing remarks**

The Chair clarified that the attributes the Committee selected today are not final. The Committee's research and discussions will help guide whether or not an attribute will be able to be included in the first iteration of continuous distribution. The next in person meeting is scheduled for March 29, 2023. Members are asked to provide feedback on whether they would like to meet in Chicago or the UNOS Headquarters in Richmond, VA, and if the March 29 date works for them.

Upcoming Meetings

- October 18, 2022
- November 15, 2022
- December 20, 2022
- January 17, 2023
- February 21, 2023
- March 14, 2023
- March 29, 2023
- April 18, 2023
- May 16, 2023
- June 20, 2023

Attendance

- **Committee Members**
  - Adam Schneider
  - Amrut Ambardekar
  - Bob Goodman, Visiting Board Member
  - Cristy Smith
  - Earl Lovell
  - Fawwaz Shaw
  - Hannah Copeland
  - JD Menteer
  - Jennifer Carapellucci
  - Jennifer Cowger
  - John Nigro
  - Jonah Odim
  - Jose Garcia
  - Kelly Newlin
  - Glen Kelley
  - Martha Tankersly
  - Nader Moazami
  - Rocky Daly
  - Shelley Hall
  - Tamas Alexy
  - Timothy Gong
- **HRSA Representatives**
  - Adriana Martinez
- **SRTR Staff**
  - Grace Lyden
  - Katie Siegert
  - Monica Colvin
  - Yoon Son Ahn
- **UNOS Staff**
  - Adam Jaboory
  - Alina Martinez
  - Darby Harris
  - Delaney Nilles
  - Eric Messick
  - Erin Schnellinger
  - Holly Sobczak
  - James Alcorn
  - Kelsi Linbald
  - Krissy Laurie
  - Laura Schmitt
  - Lauren Mauk
- **Other Attendees**
  - Neha Bansal