OPTN Heart Transplantation Committee
Meeting Summary
November 15, 2022
Conference Call

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

Introduction

The Heart Transplantation Committee met via Citrix GoToMeeting teleconference on 11/15/2022 to discuss the following agenda items:

1. 3-Month Monitoring Report: Heart Policy Modification to Address Patient Safety Following Device Recall
2. Continuous Distribution

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

1. 3-Month Monitoring Report: Heart Policy Modification to Address Patient Safety Following Device Recall

The Committee received a presentation on the 3-month monitoring report for the Heart Policy Modification to Address Patient Safety Following Device Recall. The policy changes were approved by the OPTN Executive Committee pursuant to the emergency actions language in the OPTN Bylaws. This policy was implemented on July 14, 2022 as a temporary policy and will be considered by the OPTN Board of Directors as a permanent component of OPTN policy during the December 6, 2022 Board of Directors meeting.

Data summary:

Status 2 had the greatest number of exceptions requested and transplants during the 3-months following implementation. Device recall exception submissions have not increased over time.

Summary of discussion:

Members indicated that the results were consistent with their expectations, given the short timeframe and the number of HVADs currently in use. A member felt comfortable with the spread between status 2 and status 3 and was overall satisfied with the utilization of the policy and the spread of patients across statuses. Since this exception pathway is utilized for patients with recalled devices, the Committee felt they would be able to anticipate when spikes in utilization would occur. Members felt that the policy was being utilized appropriately, and did not have concerns over innapropriate use. A member recommended reviewing operative outcome data to ensure that no major changes in patient survival were occurring.

Next Steps:

The policy will go to the OPTN Board of Directors for approval on December 5, 2022. If approved, the exception pathway will become a permanent component of OPTN policy.

2. Continuous Distribution

The Committee reviewed the timeline and next steps for developing continuous distribution. The final heart continuous distribution policy proposal is slated to go to the OPTN Board of Directors in December 2025. The Committee will publish multiple concept papers along the way engaging the community, requesting feedback, and detailing their progress and considerations. The Committee discussed the attributes that are currently in policy and discussed the potential attributes for inclusion in the initial version of heart continuous distribution that the Committee identified and voted on during the October in person meeting.

Data summary:

Attributes identified in current policy:

- Adult statuses 1-6
- Pediatric statuses 1A, 1B, and 2
- Donor – Recipient age
- Blood type
- Waiting time
- Distance from donor to transplant hospital

Attributes identified for inclusion of all continuous distribution frameworks:

- Candidates who are prior living donors
- Pediatric candidates

Attributes identified by the Committee as a priority:

- Sensitization
- Time on VAD
- Size matching
- Population density
- Prospective cross-matching
- Socioeconomic characteristics
- Congenital heart disease (CHD)
- Re-transplant

Summary of discussion:

Pediatrics

The Chair proposed the potential to break up the criteria within pediatric statuses 1A and 1B to align more with the framework and granularity of the adult heart statuses. The Chair suggested that this could be contentious insofar as it creates a higher level of benefit for some candidates, but also recognized that this modification may be more appropriate for a later iteration of continuous distribution. The Committee will also need to consider how guidance pertaining to certain diagnoses will be integrated into continuous distribution. The Vice Chair suggested that if the Committee opted not to revise the current pediatric statuses now, there may be alternative steps that could be implemented in continuous distribution. Examples include providing points for inpatient versus outpatient or providing additional points for the most severe qualifying criteria in pediatric status 1A. The pediatric subgroup will consider some of these options as part of their discussions.

Age

Members considered how points should be aligned with attributes and suggested providing points based on the candidate's age. One member cautioned that points should not be given for everything, while another noted that negative points are not going to be considered. When considering age, a member suggested providing points to patients between the ages 30 and 60 years old. This cut-off was suggested due to lower levels of compliance for patients under 30 and higher rates of post-transplant infection for patients over 60. Alternatively, a member noted that the transplant system is self-monitoring and transplant programs are responsible for their outcomes. As such, programs are disincentivized for accepting offers for patients who are unlikely to benefit from the transplant. The Chair compared this to the Lung Allocation Score (LAS) used for lung allocation where risk for complications post-transplant is considered in the score. Staff clarified that other than the distinction between pediatric and adults, age is not able to be incorporated into allocation due to concerns of discrimination. A member mentioned the distinction between chronological age and physiological age as well.

Size Matching/Size Outliers

When considering the size matching attribute, the Chair inquired if this is an attribute that should receive some level of added priority and posed whether the current size matching is insufficient in matching donors and recipients. A member countered that point, inquiring if there is data indicating that outcomes could be suboptimal if inappropriately matched. However, a member noted that size-matching aligns with the self-monitoring of centers and that programs are disincentivized from accepting an organ that is too large or small for a patient. Members reframed the discussion for patients who were excessively large or small and may have a reduced organ pool. Members suggested rephrasing this attribute to 'size outliers' or 'disadvantaged due to size.' Ultimately, the group reached a consensus that this should be reviewed and discussed by a small group to consider as an attribute.

Population Density

Members expressed some concern over this attribute. The first concern was how this attribute could be integrated into continuous distribution. The OPTN Liver and Intestine Transplantation Committee has considered this as an attribute and may be considering this within the placement efficiency goal. The Chair identified another concern, which is whether or not this is needed, inquiring if patients who are geographically isolated are at a disadvantage compared to patients in a densely populated location. While there are more transplant hospitals and more donors in a densely populated area, there are also more candidates on the waitlist, which may cause these contrasting considerations to balance out. A member suggested the example of South Floria, which is highly populated but a large portion of a transplant center's 250 nautical miles (nm) radius is in the ocean or gulf. As such, it may be possible to look at the data per capita and develop a sliding scale to provide points for this attribute. A member noted that while these considerations are important, there may not be enough data to include this in the first iteration of continuous distribution. A member referenced a report from the SRTR that included data on pre-transplant mortality rates among adults waitlisted for heart transplant by metropolitan versus non-metropolitan cities and indicated that the curves overlapped. Ultimately, the Committee opted against developing a small group to review population density at this time.

Prospective Cross-Matching

Members considered whether prospective-cross matching should be considered by the group covering sensitization and ultimately agreed for one group to cover the two topics. A member voiced concern that depending on how this attribute is considered it could incentivize programs to prospective cross-match.

Socioeconomic Characteristics

The Chair posed the question of whether there was enough data to include this attribute in the first iteration. A member suggested that it is worthwhile for the Committee to consider this attribute in a small group to review the existing literature and discuss how it could be incorporated. Members agreed that it may be unlikely to include it in the first iteration of continuous distribution, but it is still important to have this conversation now.

Congenital Heart Disease (CHD)

A member suggested that this should be considered by a small group due to the varying outcomes and nuances for these patients. A member noted that the Committee has an existing guidance document for this topic, but questioned if there are additional considerations specific to this group that need to be discussed. Members noted the impact of late transplant and worse outcomes that are specific to this population. The group agreed that it would be appropriate to have a small group to review the guidance document and existing literature and consider how it should be integrated into continuous distribution.

Retransplant

The Committee discussed if this small group was needed. Members noted that these patients are currently at status 6, likely sensitized, and often unlikely to receive a retransplant. The Committee felt it was appropriate for a more in depth discussion of how these patients should be evaluated for continuous distribution.

The Committee considered whether to increase the montly meeting cadence. They agreed to schedule the small group meetings first then proceed with additional Committee meetings to go through the small group presentations.

<u>Next steps:</u>

Members are asked to review the attributes and sign up for small groups to work on.

Upcoming Meeting

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

Attendance

- **Committee Members**
  - Adam Schneider
  - Amrut Ambardekar
  - Dmitry Yaranov
  - Earl Lovell
  - Fawwaz Shaw
  - Glen Kelley
  - Hannah Copeland
  - JD Menteer
  - Jennifer Carapelluci
  - Jennifer Cowger
  - Jonah Odim
  - Jose Garcia
  - Martha Tankersly
  - Robert Goodman
  - Rocky Daly
  - Shelley Hall
  - Tamas Alexy
  - Timothy Gong
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Grace Lyden
  - Katie Audette
  - Yoon Son Ahn
- **UNOS Staff**
  - Alina Martinez
  - Dzhuliyana Handarova
  - Eric Messick
  - Kelsi Linbald
  - Krissy Laurie
  - Laura Schmitt
  - Rachel Hippchen
  - Sara Rose Wells
  - Susan Tlusty
- **Other Attendees**
  - Neha Bansal
  - Daniel Yip