

## **OPTN Heart Transplantation Committee**

### **Meeting Summary**

**June 18, 2024**

**Conference Call**

**Rocky Daly, MD, Chair**

**J.D. Menteer, MD, Vice Chair**

### **Introduction**

The OPTN Heart Transplantation Committee met via WebEx teleconference on 06/18/2024 to discuss the following agenda items:

1. Welcome and agenda review
2. Farewell to departing members
3. Presentation and discussion: *Differences in Donor Heart Acceptance by Race and Gender of Patients on the Transplant Waiting List*
4. On-going development of the *Escalation of Status for Time on Left Ventricular Assist Device* project form
5. Open Forum
6. Closing remarks

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

#### **1. Welcome and agenda review**

The Chair welcomed the Committee members and briefly discussed the subject matter that would be discussed during the meeting.

#### **2. Farewell to departing members**

The Chair thanked the departing Committee members for their service.

#### **3. Presentation and discussion: *Differences in Donor Heart Acceptance by Race and Gender of Patients on the Transplant Waiting List***

The presentation and member discussion focused on the need to address racial and gender disparities in heart transplant outcomes, with a focus on analyzing and correcting acceptance patterns, potentially utilizing AI, improving organ distribution, prioritizing higher status for LVAD patients, and phasing in new policies over time.

#### Data summary:

Findings were presented from a study on race and gender discrepancies in heart transplant outcomes, highlighting the need for addressing disparities in care. The data showed that white women had the highest likelihood of heart acceptance, followed by black women, white men, and black men. Among the findings, the cumulative incidence showed for each offer number the likelihood of acceptance. The results showed a separation of the curves all the way to the 50<sup>th</sup> offer and the likelihood of accepting an organ more early if the patient was a white female, followed by a black women, followed by white men, and last black men. Another key takeaway is the odds of acceptance for each offer number based upon race and based upon gender. The analysis found that even at offer one, it is 24% less likely for a black

candidate to have the offer accepted compared to white candidate and this proceeds all the way up to the 16th offer at different levels of the odds ratio.

Summary of discussion:

Decision #1: No decisions were made.

The meeting discussed the disparities in heart transplant acceptance rates among different racial and gender groups.

The Committee members asked for recommendations as to how the rates of acceptance can be improved. The presenter emphasized the need for centers to analyze their own data on racial and gender acceptance patterns and develop corrective plans to address any identified disparities. The presenter also highlighted the importance of tracking decisions made at the center level and the need for self-reflection and data evaluation to drive change. The use of Artificial Intelligence (AI) functionality was suggested as a potential tool to simplify and make the decision-making process more objective. At the OPTN and SRTR levels, it was suggested that potentially reporting some of the center level data for the racial and gender acceptance patterns for organs that are ultimately accepted by a subsequent center. Also, this could be done by highlighting the transplant programs are doing a good job of addressing disparities.

The presenter raised concerns about potential biases in the organ distribution algorithm and stated their agreement with the Committee’s decision not to include a post-transplant survival attribute in this version of heart CD. The presenter suggested focusing on the risk of dying rather than post-transplant survival is appropriate because survival rates for disadvantaged groups are not always great. As a result, including it as an allocation attribute would likely just reinforce the disparities in access to donor hearts and heart acceptance rates. It was stated that consistently data is showing that the black and brown patients, women sometimes don't do as well post-transplant. So, does that mean if they're not going to do as well, the community is going to even give them fewer transplants because transplant programs do not want to mess up the numbers and we just are not going to get them because the algorithm supports not giving that to them? The presenter also mentioned blood type and high PRA. Women are more likely to have higher PRA. Higher in the patients who had a ventricular assist device (VAD), and black patients are more likely to have a VAD.

Next steps:

The Committee concurred that they would consider pursuing opportunities to address the disparities.

**4. On-going development of the *Escalation of Status for Time on Left Ventricular Assist Device* project form Open Forum**

The Committee considered what kind of timeframe makes sense with regards to time waiting balanced against medical urgency.

Summary of discussion:

Decision #1: No decisions were made.

The Committee members continued discussing a proposal to prioritize higher status for those waiting on LVAD. They have previously discussed the matter as part of the June 12 meeting. There were provided information about the potential number of candidates who would qualify for status 2 or status 3 if the

proposal was adopted, and how the increase in candidates might impact the overall waitlist mortality rates of candidates already assigned to those statuses.

The Committee was shown data indicating that candidates registered at status 2 had a 90% likelihood of getting a donor heart within one year. The likelihood of receiving a transplant decreases for statuses 3 and 4, but the chances were seen as still reasonable.

An important consideration is the amount of time a status 4 candidate with a dischargeable LVAD should wait before being eligible for status 2 or status 3. The members discussed options for consideration. The Committee is in general agreement to start with a policy proposal that would permit a status 4 candidate with a dischargeable LVAD to transition to status 3 after they have been waiting at least five years, and transition to status 2 after they have been waiting for seven years. The members also expressed interest in exploring the potential to include with the policy proposal the ability to decrease the years of waiting time based on the initial findings after the five- and seven-year options have been implemented. The members expressed interest in potentially reducing the waiting time to four and six years, based on the post-implementation monitoring results.

As part of their discussion, the Committee members reviewed the likelihood of receiving a heart transplant within a year based on different statuses and time frames on LVAD. It was pointed out that the waiting list mortality rates reflect candidates who are eventually transplanted, but also those patients who died or were delisted while waiting.

It was shown that based on status 4 patients with a dischargeable LVAD who had been waiting four or more years, 257 would be eligible to transition to status 2 or status under the proposal the Committee is considering. (The analysis was limited to using four or more years as the greatest amount of time waiting. However, the Committee was interested in using five years waiting for status 3 and seven years waiting for status 2 eligibility.) It was explained that if the number of years are reduced then the number of candidates potentially eligible for status 2 and status increases greatly. The number of potential new candidates added to the waitlist registrations for status 2 and 3 was compared to the number of candidates already assigned to those statuses. For example, at the time of the analysis there were 178 patients registered at status 2. If the Committee recommended a waiting time of five years for statuses 2 eligibility, it would result in another 156 patients being eligible, almost doubling the number of status 2 candidates. A Committee member said this large increase in the number of status 2 candidates is the danger of using a timeframe on LVAD that is not long enough. Basically, a timeframe that is too short will lead to overcrowding in the higher statuses. It was suggested that starting with waiting times of five years before status 3 eligibility and seven years before status 2 eligibility might make the most sense. It was also suggested that the Committee could consider a “phased-in” approach where the waiting times would change to four- and six-years after the changes had been implemented for at least one year.

The Committee discussed whether the five-year or seven-year eligibility period should start based on the date the candidate was registered at status 4 on the waiting list or whether it should be based on the date the device was implanted. Using device implant date is more beneficial to a candidate. For example, since the heart allocation changes implemented in October 2018, the community has come to think status 4 candidates with dischargeable LVADs do not get transplanted and as a result, transplant programs may be less inclined to register a patient with a LVAD on the waiting list. Relying on waiting list time means some candidates for whom the changes are intended to help will not receive a benefit. There are also social reasons and psychosocial barriers that might prevent an individual from being registered on the waiting list.

A member stated that the Committee is trying to address a known issue. However, the eligibility criteria cannot be so easy to meet that it might actually harm patients assigned to those statuses. An important

point for the Committee to emphasize to the community moving forward is that this will be an interim fix, and while it will help candidates it will also ensure that candidates are not harmed as a result of too many patients being assigned to status 2 or status 3. The Committee could also say that another goal is to annually reassess the number of impacted candidates with an eye towards potentially reducing the waiting time in the future. Another member agreed and said that perhaps using six years and eight-years for eligibility might be the best approach.

Next steps:

The project form will be updated to include the information discussed during the meeting. The Committee members were reminded that they also have the opportunity to discuss the subject as part of their July 2, 2024 meetings. They will discuss the number of years for eligibility and whether waiting time should reflect time registered on the waiting list or time since implant of the dischargeable LVAD.

**5. Open Forum**

There were no requests to speak during this part of the meeting.

**6. Closing remarks**

The Chair thanked the members for their participation.

**Upcoming Meeting**

- July 2, 2024
- July 16, 2024

## Attendance

- **Committee Members**
  - Rocky Daly
  - J.D. Menteer
  - Tamas Alexy
  - Amrut Ambardekar
  - Jennifer Carapellucci
  - Jennifer Cowger
  - Timothy Gong
  - Jennifer Hartman
  - Glen Kelley
  - Earl Lovell
  - Cindy Martin
  - Martha Tankersley
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Yoon Son Ahn
  - Katie Audette
  - Grace Lyden
- **UNOS Staff**
  - Yamir Chapman
  - Cole Fox
  - Kelsi Lindblad
  - Alina Martinez
  - Eric Messick
  - Sarah Roache
  - Holly Sobczak
  - Sara Rose Wells
- **Other Attendees**
  - Maria Avila
  - Khadijah Breathett
  - Hannah Copeland
  - Kevin Daly
  - Jill Gelow
  - Shelley Hall
  - Amanda Nathan