OPTN Heart Transplantation Committee
Meeting Summary
January 3, 2023
Conference Call

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

Introduction

The Heart Transplantation Committee met via Citrix GoToMeeting teleconference on 1/3/2023 to discuss the following agenda items:

1. Welcome, information, and reminders
2. Continuous Distribution: Consideration of Re-Transplant as a potential attribute

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

1. Welcome, information, and reminders

Members were reminded about the upcoming public comment cycle, which will occur from January 19 to March 15, 2023. During this time, members are asked to review the items out for public comment and engage in their regional meetings. The regional meeting schedule was shared and members can register on the OPTN website. Lastly, the Committee will meet in Richmond, Virginia for their in person meeting on March 29, 2023.

2. Continuous Distribution: Consideration of Re-Transplant as a potential attribute

In an effort to review potential attributes for continuous distribution, the Committee has divided into small groups to consider attributes in depth and present their findings and recommendations to the full Committee. As such, the re-transplant small group is presenting their findings and recommendation to include re-transplant as an attribute in the first iteration of continuous distribution. This attribute would apply to patients who are greater than or equal to one-year post-heart transplant and who meet the requirements for allograft failure or severe cardiac allograft vasculopathy (CAV) by angiography or intravascular ultrasound (IVUS) grading. These tend to be patients who are a status 4 and exclude patients who require a re-transplant due to primary graft dysfunction (PGD).

Data summary:

The Chair noted that these patients have a poor prognosis, which is why they do not qualify for a higher status, and if their medical urgency increased then their status would as well. The presenter responded that these points could accrue as the patient's condition worsened. The presenter added that developing criteria for these patients would allow for a more objective way to evaluate these patients. The Chair commented that creating a system to further define CAV may be a challenging process and could receive pushback from the community.

A small group member noted the challenge in identifying risks for this population of patients, emphasizing the potential of sudden cardiac death. The Chair pushed back that the severity of the patient's CAV may already be defined by the transplant program's willingness to list a patient in need of re-transplant. A member countered that because these patients are unlikely to be supported with a

defibrillator in the case of sudden cardiac death, they are deserving of an incremental advantage that supports them obtaining a transplant.

A member questioned the proposed definition of CAV and recommended additional data to tease out the patients who meet these qualifications but are home and stable. The presenter agreed with focusing future research on teasing out the data, but given the current information, the presenter recommends that based on the existing CAV guidelines established by the International Society for Heart and Lung Transplantation (ISHLT), the Committee should provide an incremental advantage for this small patient population (2-4% of adult heart transplants).

When considering how the points for this attribute would be characterized, a small group member recommended a binary of yes/no for either mild or severe CAV as opposed to a curve that is reflective of the severity of CAV. A member inquired if there were any questions of equity that may arise in providing points to patients who have already received a transplant over patients who have yet to receive a transplant, and how many points that should be. A member pushed back that given the small patient population, often younger patient population, with a history of compliance they should receive a small boost in priority which they could greatly benefit from.

A member questioned if the committee was moving towards providing additional points for every disease type, using patients with hypertrophic/restrictive cardiomyopathy (HCM/RCM) and patients with amyloidosis as an example. The member noted that these patients are also a small percentage of the transplant population who tend to be younger, which are similar arguments in favor of providing additional points for re-transplant as an attribute. The presenter encouraged using the data they have available on this small population to provide a benefit to those who meeting the criteria, an even smaller group, and review the policy post-implementation when more data is available.

The group discussed which goal of the continuous distribution framework this would fall into. Members mentioned post-transplant survival, candidate biology, and medical urgency but ultimately decided on medical urgency as the goal re-transplant would align with. The Vice Chair inquired if the Committee ought to review the waitlist mortality data for status 4 based on qualifying criteria. Alternatively, the presenter recommended reviewing how many patients were listed at status 4 in need of a re-transplant who were removed from the waitlist for death or other reason. The Committee reviewed the waitlist mortality data for status 4 patients and retransplant patients had the highest level of waitlist mortality compared to any other qualifying criteria.

A member inquired if they needed to provide data on outcomes in the concept paper. The member suspects pushback could arise in public comment if priority were to be given to patients with poor outcomes. Members agreed that it would be beneficial to make the distinction that this attribute applies to patients with coronary artery disease (CAD) as opposed to PGD to avoid confusion in the community.

As the Committee reached consensus to include re-transplant as an attribute, the Chair inquired if there was any opposition to this decision and heard none. Members are still interested in seeing the data for 1-year outcomes for re-transplant patients and the removal rate for death or other reasons for re-transplant patients.

Next steps:

The small group will make some updates to their document based on today's discussion and the additional data requested. Once there is a final version, staff will circulate the document to the full Committee for review.

Upcoming Meeting

- 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
  - Cristy Smith
  - Dmitry Yaranov
  - Earl Lovell
  - Glen Kelley
  - Hannah Copeland
  - JD Menteer
  - Jennifer Carapelluci
  - Jennifer Cowger
  - Jon Nigro
  - Jose Garcia
  - Kelley Newlin
  - Martha Tankersly
  - Nader Moazami
  - Robert Goodman
  - Rocky Daly
  - Shelley Hall
  - Timothy Gong
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Grace Lyden
  - Katie Audette
  - Monica Colvin
  - Yoon Son Ahn
- **UNOS Staff**
  - Alina Martinez
  - Eric Messick
  - James Alcorn
  - Kelsi Linbald
  - Krissy Laurie
  - Laura Schmitt
  - Sara Rose Wells
  - Susan Tlusty
- **Other Attendees**
  - Daniel Yip