OPTN Heart Transplantation Committee
Meeting Summary
May 18, 2021
Conference Call

Shelley Hall, MD, Chair
Richard Daly, MD, Vice Chair

Introduction

The Committee met via Citrix GoToMeeting teleconference on 05/18/2021 to discuss the following agenda items:

1. Quick updates
2. Primary Graft Dysfunction project – Data collection timeframe(s)
3. Discussion of potential new project addressing adult heart status 2 criteria

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

1. Quick updates

Summary of discussion:

UNOS staff shared that the Heart and Pediatric Committees' project *Modify Heart Policy for Pediatric Candidates and Intended Blood Group Incompatible (ABOi) Offers* was recently approved by the Policy Oversight Committee on May 12, 2021.

The National Heart Review Board for Pediatrics is scheduled to be implemented on June 15, 2021.

The Heart Committee will maintain its current schedule of meeting on the 3rd Tuesday of each month from 5:00-6:00 pm ET during the upcoming July 2021- June 2022 term.

UNOS Research staff provided an overview of the *Heart and Lung COVID-19 Diagnoses* report shared with members in the meeting materials. In summary, there were 3 waitlist additions with a COVID-19 diagnosis and 2 males with a primary diagnosis involving COVID-19 who received a heart transplant. One recipient was a Status 1 candidate and the other was a Status 2 candidate. Additional detail is included in the report.

2. Primary Graft Dysfunction project – Data collection timeframe(s)

The members discussed the most appropriate time points for collecting data elements to identify primary graft dysfunction (PGD) to include in the project's public comment proposal.

Summary of discussion:

The members considered collecting the data elements for PGD at 24 and 72 hours after heart transplant surgery. A member suggested providing a window of time around 24 and 72 hours in order to allow some flexibility of when transplant programs perform measurements. The Chair suggested having a time span of +/- 12 hours at 24 and 72 hours. Members commented that this is too wide of a window. Members agreed to a window of +/- 4 hours. A member commented that collecting the data within a specified window of time will allow for what is collected across various patients to be compared more accurately than if a value is entered from any time within the first day post operation.

The members discussed whether best or worse values should be collected and decided that identifying best or worst values during a time frame will be too burdensome for coordinators. Committee members were also concerned that outliers would skew worst or best measures. Members commented that education will be needed to ensure that programs do not report their most favorable test, but instead collect all hemodynamic data as close as possible to the time frames.

Members discussed how to define the starting point of the 24 and 72 hours, whether it should be when cross clamp occurs or when the patient arrives to the intensive care unit (ICU) following surgery. The Chair commented that it may be difficult for coordinators to find the cross clamp time and recommended using arrival to the ICU as the starting point. A member commented that cross clamp time in DonorNet® is easily found.

One member suggested collecting the data at 8:00 AM the day after the surgery to be consistent with nurse shift changes at 7:00 AM. A member commented that this would allow for too much variability in timing between patients. The Chair commented that the feedback received during public comment recommended collecting the data at 24 and 72 hours and did not believe collecting the data in the way suggested would be supported by the community.

The Chair commented that the data entered will be coming from the hemodynamic flow sheet so the time frame selected should be available on this data source to make the process easier. A member agreed that arrival at ICU is readily available whereas information reported during surgery has more variability.

The Chair proposed 24 +/- 4 and 72 +/- 4 hours from arrival to ICU for collecting the hemodynamic and inotrope information. The members supported this recommendation unanimously. The members decided to include a question in the public comment document to determine whether or not the community would prefer to have the starting point as the release of cross clamp.

3. Discussion of potential new project addressing adult heart status 2 criteria

Summary of discussion:

The Chair commented that there is growing community concern about the increase in candidates with intra-aortic balloon pumps (IABP) and decrease of candidates with left ventricular devices (LVADs) at Status 2. The Committee has previously attempted to remedy the increase in candidates listed at Status 2 by exception with the Status 2 guidance document.

The Chair commented that the waiting time for candidates with LVADs has decreased when comparing pre and post policy implementation eras. The longer a candidate is supported by a LVAD, the more likely they will experience complications.

The number of candidates with IABPs at time of listing have doubled pre to post policy implementation era whereas the number of candidates with LVADs has decreased. At transplant, there has been a substantial increase in candidates with IABPs and a decrease in candidates with LVADs when comparing pre and post policy implementation eras. There is a concern that IABPs are being used in place of inotropes in order to be eligible for a higher status. The Chair asked the members if these changes warrant a policy revision intended to control the use of IABPs.

A member raised a concern that regardless of the approach taken, workarounds will be found to give patients an advantage. The approach taken will need to be agile to accommodate changes in device technology.

A member asked if the candidates with IABPs were listed at Status 2 by standard criteria or by exception. The Chair responded that more IABP candidate were listed at Status 2 by exception. A member raised a concern that revising policy may not address those who are listed at status by exception.

The Chair commented that a simple solution might be requiring evidence of inotrope failure. A member commented that this will be hard to define. The Chair also suggested adding term limits for statuses.

A member asked how patient outcomes are being impacted. UNOS staff will include post-transplant outcome data for recipients with LVADs in an upcoming manuscript. Another option is to complete a monitoring report that includes additional data sooner than the 3 year monitoring report that will be completed in October 2021. UNOS staff suggested providing additional data as part of a 3-month monitoring report for the adult Status 2 guidance document that was implemented in February. Member agreed to this approach.

A member commented that patient outcomes both on the waitlist and post-transplant, stratified by IABP and LVAD, need to be evaluated before recommending any policy revisions. Although behaviors may have changed, this change may be creating better outcomes for patients overall.

A member suggested making it more difficult to apply for an extension for Status 2 with IABP. The Chair commented that this would require either a culture change of the regional review boards to be more restrictive or a change in policy. A member commented that they have recently seen a couple decisions against renewing Status 2 exceptions which has been uncommon. They noted that this may indicate that a culture shift is already occurring.

The members reviewed waitlist mortality data included in the 2 year monitoring report. It was noted that overall, waiting time has decreased but waiting time at Status 2 has increased, although the increase is not statistically significant. The members reviewed post-transplant survival by status data from the same report. A member commented that Status 4 patients are likely to have better post-transplant outcomes than recipients listed at more urgent statuses but are less likely to receive an offer than candidates at more urgent statuses. A member commented that sicker patients are less likely to be optimized for transplant which impacts their long term outcomes.

Next steps:

UNOS staff will prepare data to compare waitlist and post-transplant outcomes for recipients with IABPs and LVADs.

Upcoming Meeting

- June 15, 2021

Attendance

- **Committee Members**
  - Arun Krishnamoorthy
  - Adam Schneider
  - Cindy Martin
  - David Baran
  - Donna Mancini
  - Hannah Copeland
  - J.D. Menteer
  - Kelly Newlin
  - Jonah Odim
  - Rocky Daly
  - Ryan Davies
  - Shelley Hall
  - Rachel White
  - Michael Kwan
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Andrew Wey
  - Katie Audette
  - Monica Colvin
  - Yoon Son Ahn
- **UNOS Staff**
  - Chris Reilly
  - Elizabeth Miller
  - Eric Messick
  - Janis Rosenberg
  - Keighly Bradbrook
  - Leah Slife
  - Sara Rose Wells
  - Susan Tlusty