

## **OPTN Heart Transplantation Committee**

### **Meeting Summary**

**November 17, 2020**

**Conference Call**

**Shelley Hall, MD, Chair**

**Richard Daly, MD, Vice Chair**

### **Introduction**

The Committee met via Citrix GoToMeeting teleconference on 11/17/2020 to discuss the following agenda items:

1. Project updates
2. January – March, 2021 Regional meetings

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

#### **1. Project updates**

UNOS staff provided updates on Heart Committee projects.

##### Summary of discussion:

##### *Guidance Addressing the Use of Pediatric Heart Exceptions*

This project will be voted on during the upcoming Board of Directors (BOD) meeting.

The Vice Chair presented the proposal to the Board Policy Group (BPG) on November 13<sup>th</sup>. The BPG members voted to have the guidance be considered on the consent agenda. They also voted to recommend the Board approve guidance document.

UNOS staff shared that the proposal was well received by the BPG members. One BPG member raised question about whether patients will still have exception pathways if not good candidates for ventricular assist devices (VADs) and was ensured that the exception pathway remains.

Another BPG member commented that the transplant societies associated with pediatric patients and their families felt their voices were heard when the Workgroup was drafting the guidance. This BPG member also reiterated a concern about the need to continue exploring the root cause for exception requests. The Committee will continue to review how to address exception requests in future projects in addition to reviewing exception requests as part of the monitoring plan for the National Heart Review Board for pediatric candidates.

##### *Guidance and Policy Clarifications Addressing Adult Heart Allocation Policy*

The BPG voted to add this proposal to the discussion agenda and also voted to recommend the BOD approve.

UNOS staff shared that BPG members commented that the policy changes and guidance appear to be about standardization and supported the changes.

Another BPG commenter noted the need to be very careful to avoid unintended consequences in patient care with changing the timeframe of when hemodynamics are monitored from 90 to 180 days but acknowledged that monitoring is a programmatic decision.

Another BPG member raised a concern that 14 days at Status 2 is not enough time because patient has to be made sicker to collect hemodynamic data demonstrating that the status is still appropriate and suggested extending the timeframe to 30 days. This subject is not addressed in the proposal and UNOS staff is following up to ensure the commenter has a clear understanding of the scope of the proposed changes and to clarify this suggestion is unrelated. The Chair shared that there is sentiment in the community that Status 2 needs to be more restrictive and this will be a part of future Committee work.

#### *Data Collection to Monitor Primary Graft Dysfunction in Hearts*

The *Request for Input* document is currently under review but feedback should be received shortly. Next, the document will be reviewed by cross department collaborators at UNOS.

The Subcommittee will begin focusing on addressing the data collection principles, working through the Data Advisory Committee (DAC) checklist, and planning for remainder of project. Upcoming meetings are November 30<sup>th</sup> and December 17<sup>th</sup>.

#### *Review of Extension Requirements in Adult Heart Allocation Policy*

UNOS staff is presenting the initial project idea to DAC on December 14<sup>th</sup> followed by submitting the project form to the Policy Oversight Committee (POC) at the end of December for review at the POC meeting on January 13<sup>th</sup>. The Committee will vote to send the proposal to public comment in April and then the proposal will go to public comment in August of 2021.

The Chair noted that it requires a year minimum to make policy changes.

#### *Modifications to Pediatric Heart Policy Addressing Fontan Patients and Changes to Heart Diagnoses Codes*

This new project came out of the work from the Pediatric Heart Workgroup and is related to the status assignment for pediatric Fontan candidates. A project form needs to be completed and this project idea needs to be presented to DAC. A Workgroup may be formed to ensure there are pediatric representatives involved in the project's development. The additional diagnoses relating to congenital heart disease (CHD) previously discussed with Committee leadership may be included in this potential proposal.

The Vice Chair commented that the intent of the project is to improve the consistency between adult and pediatric statuses. He commented that a 17-year-old Fontan candidate is assigned Status 2 which is equivalent to adult Status 5 or 6. However, 18-year-old Fontan candidates are listed at adult Status 4 which is more equivalent to pediatric Status 1B. The guidance going to the BOD maintains a pathway for Fontan candidates seeking 1B by exception but it was determined that this disparity should be carried forward and addressed by a policy modification. This will allow pediatric Fontan candidates to be listed at 1B through standard criteria.

A member commented that these patients are high risk for complications and some are unable to receive VADs. Pediatric patients are able to seek exceptions but it is more complicated for Fontan adults as there are various status levels which may cause complications and require guidance.

## **2. January – March, 2021 Regional meetings**

Summary of discussion:

Due to the COVID-19 surge, all upcoming regional meeting will be virtual. The Committee members were presented the list of dates. UNOS staff will reach out to each regional representative to confirm they are available to virtually present the PGD project to their region. Specific timing has not been established.

UNOS staff shared a list of upcoming Committee meetings. The Chair commented that most work through the end of the year will be completed in the Subcommittees. She mentioned that due to this, the December 15<sup>th</sup> meeting may be cancelled.

#### **Upcoming Meetings**

- December 15, 2020
- January 19, 2021
- February 16, 2021

## Attendance

- **Committee Members**
  - Adam Schneider
  - Arun Krishnamoorthy
  - Cindy Martin
  - David Baran
  - Donna Mancini
  - Greg Ewald
  - Hannah Copeland
  - J.D. Menteer
  - Jonah Odum
  - Jose Garcia
  - Kelly Newlin
  - Michael Kwan
  - Mike McMullan
  - Rachel White
  - Rocky Daly
  - Ryan Davies
  - Shelley Hall
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Katie Audette
  - Monica Colvin
  - Yoon Son Ahn
- **UNOS Staff**
  - Eric Messick
  - Janis Rosenberg
  - Keighly Bradbrook
  - Leah Slife
  - Sara Rose Wells
  - Sarah Konigsburg
- **Other Attendees**
  - Hannah Byford