

## **OPTN Heart Transplantation Committee**

### **Meeting Summary**

**June 15, 2021**

**Conference Call**

**Shelley Hall, MD, Chair**

**Richard Daly, MD, Vice Chair**

### **Introduction**

The Committee met via Citrix GoToMeeting teleconference on 06/15/2021 to discuss the following agenda items:

1. Goodbyes to departing Committee members
2. Develop Measures for Primary Graft Dysfunction
3. Adult Heart Policy Status Extension Requirements

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

#### **1. Goodbyes to departing Committee members**

##### Summary of discussion:

The Chair thanked the departing members for their service. UNOS staff noted that the National Review Board for Pediatrics went into effect on June 15 and acknowledged the work of the departing former past Chair in its development.

UNOS staff reminded members to complete the required educational modules and sign the conflict of interest and confidentiality agreements. If the members need assistance, they were encouraged to reach out to [volunteer@unos.org](mailto:volunteer@unos.org).

#### **2. Develop Measures for Primary Graft Dysfunction**

The Chair provided an overview of the Develop Measures for Primary Graft Dysfunction (PGD) project's progress, sharing that a list of data elements was initially developed and then shared with the community to gain feedback. This feedback was reviewed and informed modifications to the initial list of data elements. The Committee voted to send the proposal for public comment in August.

##### Summary of discussion:

The Chair reviewed the proposed data elements, values to be collected, descriptions, and rationale. She reminded the members that this data will be collected on all heart recipients to promote the validity of the dataset. The Data Advisory Committee supported collecting this data on all heart recipients.

UNOS staff confirmed that the Primary Graft Dysfunction Subcommittee (Subcommittee) recommended collecting discrete values for left ventricular ejection fraction (LVEF), right atrial pressure (RAP), pulmonary capillary wedge pressure (PCWP), pulmonary artery systolic pressure and diastolic pressure, and cardiac output.

The Chair reviewed the inotrope and vasopressor ranges proposed by the Subcommittee. Collecting ranges, rather than discrete values, was supported by the community during the request for feedback. The intention for collecting ranges is to reduce burden. The Chair shared that information on Nitric

Oxide and Flolan will be collected as “yes or no” because there is a lot of variability in administration and standards of care.

The Chair noted that “airway dehiscence” is being recommended for removal from the Heart Transplant Recipient Registration (TRR) form as part of the proposal.

The Chair commented that the PGD data will be collected 24 hours (+/- 4 hours) after the candidate arrives in the intensive care unit (ICU) and again at 72 hours (+/- 4 hours) following ICU arrival. Common feedback from the community was to collect the data at 24 and 72 hours.

A member of the public questioned how the data will be used. The Chair commented that the OPTN will use the data to analyze the existence, presence, and severity of PGD. The member of the public questioned the definition of PGD included in the data element’s description. The Chair commented that the description provided is based on existing literature. The member of the public recommended removing the “PGD yes or no” data element because users may enter “no” inaccurately and then the remaining data would not be collected. The Chair commented that all of the data elements will be collected on all heart recipients. UNOS Research staff commented that the information collected will be valuable when there is enough data to evaluate.

The member of the public raised a concern about the use of the data and whether it would be used for internal assessment or would be reported publicly. He commented that the data collected is dynamic and fluctuates which may incentivize a program to choose numbers that depict better outcomes if the data is public and could be used to compare transplant programs. A member recommended including a clause to the data collection instrument about why the data is collected and how it will be used.

The members voted on whether to submit the data collection proposal for public comment. No opposition was voiced.

### **3. Adult Heart Policy Status Extension Requirements**

The Committee reviewed the proposed policy modifications and voted to send the proposal for public comment in August.

#### Summary of discussion:

#### *Policy 6.1.A.iii: MCSD With Life Threatening Ventricular Arrhythmia*

UNOS staff shared that an additional Status 3 criteria is being proposed to allow a “landing spot” for patients who are not extended under policy 6.1.A.iii but still should be listed at a higher urgency than Status 6. This new policy was modeled off of *Policy 6.1.A.i Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)* and *Policy 6.1.C.ix VA ECMO after 7 Days*.

UNOS staff asked if the new criteria should address candidates who are eligible for Status 1 under *Policy 6.1.A.iii: MCSD With Life Threatening Ventricular Arrhythmia* due to being on a biventricular assist device (BiVAD), those who are anti-arrhythmic intravenous (IV) therapy, or both. The Chair confirmed that both candidates who are receiving BiVAD support and IV anti-arrhythmic therapy should be eligible for the new Status 3 policy.

UNOS staff commented that the proposed extension language for policy 6.1.A.iii requires the candidate to remain hospitalized on IV anti-arrhythmic therapy which would not apply to the candidates who were eligible for this status because they are being supported by a BiVAD. Members commented that candidates with non-dischargeable BiVADs should remain at Status 1 as they would be eligible for the status under policy 6.1.A.ii. A member clarified that the candidate described would only be eligible for Status 1 under policy 6.1.A.ii if the BiVAD was surgically implanted. If the candidate has a TandemHeart

that was placed for ventricular arrhythmias, they would be eligible for Status 2 because they have a percutaneous BIVAD. The Chair agreed and commented that since the candidates who are eligible for policy 6.1.A.iii already have a mechanical circulatory support device (MCSD) supporting their left ventricle, a percutaneous right ventricular device (RVAD) is added to address the ventricular arrhythmia.

The members agreed to propose language that if the program does not apply for an extension for Status 3 under policy 6.1.A.iii, the candidate can be downgraded to the corresponding Status 3 being proposed. The members agreed that the program can determine if there is another more appropriate status that their candidate would be eligible for because of their specific support devices.

UNOS staff shared the proposed policy language for the new Status 3 criteria. The Chair agreed with the language and the 7 day timeframe.

UNOS staff confirmed that the initial status timeframe should be reduced from 14 to 7 days.

#### *6.1.A.i Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO) and 6.1.A.ii Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device*

UNOS staff shared proposed modifications to policies 6.1.A.i and 6.1.A.ii that add language that the candidate needs to remain hospitalized in order to be eligible for the status. This change is intended to make current requirements clearer. The members agreed with the additional language as proposed.

#### *Policy 6.1.C.iv: Mechanical Circulatory Support Device (MCSD) with Pump Thrombosis*

UNOS staff confirmed that “in the absence of intracardiac thrombus or significant carotid artery disease” applies to all conditions listed as follows “Transient Ischemic Attack (TIA) lasting less than 24 hours or Reversible Ischemic Neurologic Deficit (RIND) lasting less than 72 hours (as observed by symptoms such as, but not limited to unilateral facial weakness, vision problems, and/or slurred speech), Cerebrovascular Accident (CVA), or peripheral thromboembolic event in the absence of intracardiac thrombus.”

UNOS staff asked for the rationale for proposing to extend this status from 14 to 30 days. UNOS staff noted that other Status 3 criteria have a 14 day initial timeframe. The Chair commented that pump thrombosis is one of the most devastating MCSD complication. A member commented that based on the median days to transplant for candidates at Status 3, the candidates listed at this status will likely receive a transplant before needing to extend.

#### *Policy 6.1.C.vi: Mechanical Circulatory Support Device (MCSD) with Device Infection*

UNOS staff confirmed that the members want to propose requiring IV antibiotics in order for candidates to be extended at this status. A member commented that the intention is to indicate that the candidate is still being managed for a severe infection. UNOS staff noted that only some of the criteria in **Table 6-1: Evidence of Device Infection** requires IV antibiotics. The Chair commented that in the case of recurrent debridement or positive culture, which do not require IV antibiotics to qualify initially, IV antibiotics at time of extension will be required.

A member commented that requiring IV antibiotics to extend will limit the potential that a candidate is able to be eligible for the status because they were bacteremic and treated with antibiotics at any point in time. The intention is to limit this status to candidates who are still experiencing issues with infections.

A member of the public commented that candidates requiring recurrent debridement for driveline infections are at very high risk. The Vice Chair agreed that recurrent debridement should qualify them for the status.

After discussing how to establish a timeframe for the infection, the members ultimately decided to add the following extension language “After the initial qualifying time period, this status can be extended by the transplant program by submission of another Heart Status 3 Justification Form if the candidate continues to meet the criteria and has experienced the condition within the timeframe established in Table 6-1: Evidence of Device Infection or currently requires IV antibiotics.” The Chair commented that if public comment responses indicate that this language is confusing, the requirements could be further specified by adding an additional column to the table to outlines the extension criteria for each type of infection.

A HRSA representative raised a concern that some pathogens will become resistant to oral antibiotics which would require the use of IV antibiotics. The Chair commented that allowing oral antibiotics as eligibility criteria would not be restrictive enough since oral antibiotics are administered liberally.

#### *6.1.C.v Mechanical Circulatory Support Device (MCSD) with Right Heart Failure*

UNOS staff confirmed that the proposed timeframe will be extended from 14 to 90 days.

The members voted on whether to submit the policy proposal amending adult heart extension requirement for public comment. No opposition was voiced.

#### Next steps:

UNOS staff shared that public comment begins on August 3<sup>rd</sup> and ends on September 30<sup>th</sup>. The Committee will receive an update about comments received in September, the Subcommittee will address the comments and make any modifications, and then the full Committee will vote on final proposals in October to send to the Board of Directors for approval in December.

#### **Upcoming Meeting**

- July 20, 2021

## Attendance

- **Committee Members**
  - David Baran
  - Donna Mancini
  - Greg Ewald
  - J.D. Menteeer
  - Jonah Odum
  - Jose Garcia
  - Kelly Newlin
  - Laura DePiero
  - Michael Kwan
  - Mike McMullan
  - Rocky Daly
  - Ryan Davies
  - Shelley Hall
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Katie Audette
  - Monica Colvin
  - Yoon Son Ahn
- **UNOS Staff**
  - Chris Reilly
  - Eric Messick
  - Janis Rosenberg
  - Keighly Bradbrook
  - Sara Rose Wells
  - Sarah Konigsburg
  - Susan Tlusty
- **Other Attendees**
  - Amrut Ambardekar
  - Fawwaz Shaw
  - Jennifer Carapellucci
  - Nader Moazami