

**OPTN Heart Transplantation Committee  
Primary Graft Dysfunction Subcommittee  
Meeting Summary  
December 17, 2020  
Conference Call**

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

## **Introduction**

The Primary Graft Dysfunction Subcommittee met via Citrix GoToMeeting teleconference on 12/17/2020 to discuss the following agenda items:

1. Review changes made to Request for Input document as a result of internal review
2. Discuss list of heart devices and what should be removed and added

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

### **1. Review changes made to Request for Input document as a result of internal review**

The *Request for Input* document was reviewed and approved by UNOS leadership. The Subcommittee members reviewed and approved the minor edits made during the review process.

#### Summary of discussion:

Following feedback from UNOS leadership, the International Society for Heart and Lung Transplant (ISHLT) consensus definition of primary graft dysfunction (PGD) was included in the *Request for Input* document as an appendix.

UNOS staff shared that the data elements the Subcommittee agreed on during the previous meeting were updated in the document. UNOS staff also confirmed that the description of PGD that the Subcommittee had developed as part of the previous call can be included on the data collection form in order to provide guidance to the person entering data.

UNOS staff shared the new content added to the *Consideration of risk factors as potential data elements for collection* section. The focus of the new paragraph is to ask for community's input on the most important time points for collecting warm ischemia information during procurement. The members suggested requesting this feedback for all donors, not just donation after cardiac death (DCD) donors. The document was edited to remove the DCD specification in the third sentence.

The members discussed potential edits to the section of the Transplant Recipient Registration (TRR) form included in Exhibit 1. The members were informed that the data elements discussed for removal or modification previously cannot be changed because the information is used for other purposes. The Chair raised a concern about a need to update these fields in order for the form to be useful.

UNOS staff thanked the Subcommittee members for their work on the development of this project and document.

#### Next steps:

UNOS staff will poll the members' availability to schedule the next meeting.

## **2. Discuss list of heart devices and what should be removed and added**

The members discussed and suggested modifications to the list of heart devices available on the OPTN website.

### Summary of discussion:

Heart transplant candidates may qualify for certain heart statuses if supported by mechanical circulatory support devices (MCS). On the OPTN website, the MCSs are organized into four categories: dischargeable ventricular assist devices (VADs), non-dischargeable VADs, percutaneous devices, and total artificial hearts. Heart status justification forms capture the device names of those on the list, however, there are no device brands listed for venoarterial extracorporeal membrane oxygenation (VA-ECMO) or intra-aortic balloon pumps (IABP).

The members reviewed the current list of devices and agreed that it needs updating as several of the devices are no longer used. A member raised a concern about the ease of updating this pick list from a programming perspective. A UNOS IT staff member confirmed that adding new devices is low effort and will research the frequency of the devices suggested for removal in order to confirm the option is no longer needed.

The members suggested the following changes to the list of devices.

### **Dischargeable VADs**

- Remove:
  - Heartsaver VAD
  - ReliantHeartAssist 5
  - ReliantHeart aVAD
  - Worldheart Levacor

### **Non-Dischargeable VADs**

- Remove:
  - Abiomed AB5000
  - Abiomed BVS 5000
  - Medos
  - Terumo Duraheart
  - Thoratec IVAD
  - Thoratec PVAD
  - Toyobo
  - Ventracor VentrAssist
- Add:
  - Sorin Revolution

### **Percutaneous Devices**

- Remove:
  - Impella Recover 2.5
- Add:
  - Cardiohelp
  - Impella 5.5
  - Sorin Revolution
- Investigate:

- Combining all left ventricle Impellas (CP, 5.0, 5.5) and keep Impella RP separate or combine all Impellas and designate whether the device supports the left or right ventricle

### **Total Artificial Hearts**

- Remove:
  - AbioCor

The members also considered making the list more consistent in labeling by including the brand, device name, and sizing if applicable.

UNOS staff suggested establishing a schedule for regular review. Members agreed that annual revisions would be appropriate.

#### Next steps:

UNOS Research staff will look at the “other- specify” entries and send suggestions for other devices to consider adding to the list. UNOS IT staff will provide counts of devices in use to confirm whether devices should be removed.

### **Upcoming Meetings**

- January 28, 2021

## Attendance

- **Subcommittee Members**
  - Donna Mancini
  - Hannah Copeland
  - J.D. Menteer
  - Shelley Hall
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Yoon Son Ahn
- **UNOS Staff**
  - Eric Messick
  - Janis Rosenberg
  - Julia Chipko
  - Keighly Bradbrook
  - Sara Rose Wells
  - Sarah Konigsburg