OPTN Heart Transplantation Committee
Pediatric Heart Workgroup
Meeting Summary
October 27, 2020
Conference Call

Ryan Davies, MD, Chair

Introduction

The Workgroup met via Citrix GoToMeeting teleconference on 10/27/2020 to discuss the following agenda items:

1. Review briefing paper

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

1. Review briefing paper

The Workgroup discussed the *Guidance Addressing the Use of Pediatric Heart Exceptions* briefing paper.

Summary of discussion:

UNOS staff provided a recap of the decisions and edits made to the Guidance as a result of discussing public comment feedback at the previous Workgroup meeting.

The members discussed the 5-10 kilogram (kg) dilated cardiomyopathy (DCM) candidate category included in the Guidance. A member commented that a lot of feedback was received about these patients. The member commented that these smaller candidates have increased risks associated with placing ventricular assist devices (VADs) and for these sicker and smaller patients, a transplant may be more appropriate than a VAD. Managing these patients with inotropes rather than a VAD may be best for some candidates depending on their condition and this clinical decision should not limit them from being eligible for a higher status. The members supported the Guidance as written since it describes a candidate that is not being well supported, may not be a good candidate for a VAD, and should be eligible for a higher status because of their medical urgency as evidenced by the criteria included in the Guidance.

The members discussed the Status 1B exception eligibility criteria for Fontan candidates. Public comment feedback was received that raised concern that the criteria may be too inclusive. The Chair commented that if a Fontan candidate is listed, it is likely due to complications related to their Fontan. The members agreed that the Guidance should be further clarified to state that complications are required to be eligible for Status 1B by exception. Hospitalization will only be required to be eligible for Status 1A by exception. The Chair commented that Fontan candidates typically need exceptions due to the rate in which they decline medically. The members decided to consider a revision of policy to increase the status of all Fontan candidates, who are assigned as Status 2 through standard criteria, in a potential Heart Transplantation Committee project and narrow the guidance for Status 1B eligibility to Fontan candidates that are experiencing complications and are receiving therapy for those complications.

A member suggested referencing the *Review Board Guidance for Adult Congenital Heart Disease (CHD) Exception Requests* to help develop language to narrow the Fontan Status 1B by exception criteria. This

document was used as a guide when developing the pediatric guidance. The members agreed to include more criteria describing complications and need for ongoing treatment in the eligibility criteria for Fontan candidates seeking Status 1B by exception.

UNOS staff asked if this change is a logical outgrowth of what went to public comment. The Chair commented that it is, and will only narrow the guidance language. The Chair will provide language and UNOS staff will send out a revised version of the Guidance to the members for final review.

In response to a comment requesting more clarity around hospital admission for coronary allograft vasculopathy (CAV) and retransplant candidates seeking Status 1A exception, the members decided to add language that states hospitalization is required for all Status 1A exceptions and provide a reference to the supporting policy.

In response to a comment about the inclusion of triple vessel disease as a criterion for Status 1A by exception eligibility in the CAV and retransplant guidance, the members agreed to further define this diagnosis by changing the language to "a diagnosis of severe CAV similar to ISHLT CAV 3 grade." The members agreed that "severe CAV" is more recognizable than triple vessel disease. The inclusion of the ISHLT CAV 3 grade definition provides more clinical guidelines about what qualifies as severe CAV.

A member suggested including the review of this Guidance as a component of the training and onboarding of National Heart Review Board for pediatric candidates members.

The members agreed to remove the language in the proposal that suggests VADs are placed by some programs in order for their patients to achieve higher status. UNOS staff and members felt this statement was not needed to support the rationale of the DCM Guidance.

UNOS staff asked if the member had additional resources, articles, or information to support that Fontan patients are at higher risks and are more medically urgent than the status assigned through standard criteria. Members commented that the language included is strong as is but would send along any other articles that support this section of the briefing paper.

UNOS staff shared that the Guidance would be voted on by the Heart Committee on October 29th and thanked the Workgroup members for their work.

Next steps:

UNOS staff will incorporate the edits discussed and send a revised version of the Guidance to the Workgroup for their final review.

Upcoming Meeting

- November 24th, 2020 (tentative)

Attendance

- **Workgroup Members**
  - Melanie Everitt
  - Rachel White
  - Rocky Daly
  - Ryan Davies
  - Warren Zuckerman
  - William Dreyer
- **HRSA Representatives**
  - Adriana Martinez
  - Jim Bowman
- **SRTR Staff**
  - Katie Audette
  - Yoon Son Ahn
- **UNOS Staff**
  - Eric Messick
  - Janis Rosenberg
  - Keighly Bradbrook
  - Sara Rose Wells
  - Sarah Konigsburg
  - Susan Tlusty