OPTN Thoracic Organ Transplantation Committee
Pediatric Heart Workgroup
Meeting Summary
May 26, 2020
Conference Call

Ryan Davies, MD, Chair

Introduction

The Pediatric Heart Workgroup met via Citrix GoToMeeting teleconference on 05/26/2020 to discuss the following agenda items:

1. Update of National Heart Review Board for Pediatrics proposal – June 8, 2020 Board of Directors meeting
2. Finalize Guidance for Pediatric Heart Exception Requests

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

1. Update of National Heart Review Board for Pediatrics proposal – June 8, 2020 Board of Directors meeting

The Chair shared that he presented the National Heart Review Board (NHRB) for Pediatrics to the Board Policy Group.

Summary of discussion:

The Chair shared that the NHRB for Pediatrics was approved by the Board Policy Group and will be added to the discussion agenda and voted on by the Board at the June 8th meeting. UNOS Staff shared that a Board member plans to provide an endorsement from Transplant Family at the meeting.

2. Finalize Guidance for Pediatric Heart Exception Requests

The Chair led discussion to finalize the Coronary Allograft Vasculopathy (CAV) and Retransplantation portion of the pediatric heart exception request guidance. He also provided an overview of suggestions from ACTION network.

Summary of discussion:

Coronary Allograft Vasculopathy (CAV) and Retransplantation

The Chair asked the Workgroup if criteria other than history of cardiac arrest should be included for Status 1A for CAV patients seeking retransplantation.

A member responded by stating severe single or triple vessel disease or severe hemodynamics could warrant 1A as these patients are at risk for sudden death; however, defining the severity is challenging since there is no standardized way of reviewing the coronaries specifically.

A member agreed that the criteria described in Table 4 for Status 1A could potentially be expanded to include patients with bad hemodynamics or severe vessel disease since this patient population is small and are particularly difficult to manage.

The Chair asked if patients who have been revascularized should qualify as 1A. Members agreed to expand the current 1A criteria in the guidance document to include "signs or symptoms placing patients at a high risk for sudden cardiac death including any of the following: a diagnosis of severe triple vessel disease or significant restrictive hemodynamics, non-sustained ventricular tachycardia, unexplained syncope, or inotrope dependency" and keep the revascularization criteria at 1B.

Members had no other edits to Table 4.

Standardizing Information for Exception Requests

The Chair asked the Workgroup if they believed it would be helpful to provide guidelines on information that should be included in an exception request. Members agreed to include this in the guidance document. A member shared that similar templates are being created for adult exception requests. A member commented that providing a template would help the Regional Review Boards as well. The Chair will draft a template.

Dilated Cardiomyopathy (DCM)

The Chair shared that the ACTION Network has a less prescriptive version of guidelines for Dilated Cardiomyopathy (DCM), focusing solely on if the patient has evidence of clinical deterioration and if the patient is high-risk for Ventricular Assist Device (VAD) support. The Chair asked the Workgroup if they believe that a less prescriptive version, similar to the ACTION Network's, is better than the more prescriptive version the Workgroup already drafted. The Chair reminded the Workgroup that their goal was to reduce the number of patients at Status 1A, which is one of the purposes in being more prescriptive.

A member who has participated on a Review Board commented that they prefer a more prescriptive version of the guidance. Other members agreed that the guidance document should be less vague.

A member commented that the guidance document should outline why a patient is high risk for VAD support including recurring strokes, gastrointestinal bleeding, dialysis dependency, and heart-kidney transplant.

The Chair asked if the Workgroup prefers to replace their existing statement regarding right ventricular (RV) failure with the ACTION Network's statement that RV failure is not generally a contraindication to VAD placement in children. Members preferred the ACTION Network's version. A concern was raised about smaller, less experienced hospitals requesting an exception using this criteria rather than providing LVAD support to the patient. The members chose the use the ACTION Network language in the guidance for public comment and see what feedback is received. A member commented that if a smaller transplant hospital includes their reasoning in their narrative, the patient will still be considered for an exception. The Chair suggested having a specific question about the RV failure language included during public comment.

Hypertrophic/Restrictive (HCM/RCM) Cardiomyopathy

The Chair asked the Workgroup if the current language in the guidance document regarding HCM/RCM should be changed to be more similar to the ACTION Network's statement "or recurrent prolonged runs of hemodynamically significant arrhythmias not controlled by medical therapy." Members agreed that including arrhythmias was reasonable. The member suggested removing "recurrent" as a descriptor of sudden death. A member commented that they liked the inclusion of "not controlled by medical therapy."

The Chair questioned how to best define "rapidly increasing" in regard to pulmonary vascular resistance (PVR) and asked the Workgroup for their thoughts about removing this language. Members agreed to remove this language due to concerns around accurately defining what qualifies as rapidly increasing.

Single Ventricle Heart Disease

The Chair asked the Workgroup if including language about the patient actively receiving therapy should be included in the criteria in Table 3 for patients with single ventricle heart disease seeking exceptions. The members agreed to this addition.

The Chair asked if the members had any additional comments, concerns, or questions.

A member raised a concern about DCM patients that weigh less than 10 kilos and questioned the criteria stating that they must be on at least two inotropes instead of high dose inotropes. The members agreed that Table 1 should be edited to have the same dosing criteria for patients less than 5 kilos and less than 10 kilos. A member asked how the criteria for patients less than 5 kilos is different than the criteria for patients less than 10 kilos. The Chair explained that the less than 10 kilos group also needs to show signs of some type of deterioration.

A member asked if the guidance will include a disclaimer that states the document's purpose. The Chair responded that this will be included as an introduction.

A member raised a concern around the equity of some programs requesting exceptions while other programs have patients that have similar attributes that do not request a higher status. The Chair commented that language about all patients being considered as individuals will be included in the introduction. The Chair will draft copy and send to the Workgroup to review.

Next steps:

The Chair will send a draft of the introduction to the Workgroup to review.

The full Thoracic committee will vote to send the guidance to public comment on 5/28/2020. Public comment starts August 4th and runs through early October. The Workgroup will provide a status update about public comment results so far on 9/22/2020.

The Chair suggested cancelling the July and August meetings.

The Chair thanked the Workgroup for their hard work.

Upcoming Meetings

- September 22, 2020: Pediatric – Heart Workgroup (teleconference) – 4:00 to 5:00 pm (EDT) – Status update of guidance document during public comment
- October 27, 2020: Pediatric – Heart Workgroup (teleconference) – 4:00 to 5:00 pm (EDT) – Review public comment and regional meeting feedback concerning guidance document