

**OPTN Heart Transplantation Committee
Pediatric Heart Workgroup
Meeting Summary
September 22 2020
Conference Call**

Ryan Davies, MD, Chair

Introduction

The Workgroup met via Citrix GoToMeeting teleconference on 09/22/2020 to discuss the following agenda items:

1. Review public comment feedback to date

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

1. Review public comment feedback to date

The Workgroup discussed committee and public comment feedback received in response to the *Guidance Addressing the Use of Pediatric Heart Exceptions* proposal.

Summary of discussion:

The Workgroup was given a summary of sentiment votes received in the regional meetings to date. The majority of voters have expressed support.

General Feedback

Positive feedback received so far during regional meetings, the Pediatric Transplantation Committee, and through submissions of comments on the OPTN website include that this guidance is timely, it will assist in increasing the consistency of review, and agreement that reviewers should have pediatric experience. One commenter from the Pediatric Transplantation Committee thanked the workgroup for being inclusive of information from the Advanced Cardiac Therapies Improving Outcomes Network (ACTION) as well as other pediatric transplant groups when drafting the proposal. There was also agreement that developing guidance, rather than policy, was the correct path to take when addressing exception requests.

Criticisms include that there needs to be more clarity in some of the criteria and formatting, the guidance needs to match best practices and not further promote inequity in the system, the guidance should be revised based on broader pediatric heart transplant consensus, and there needs to a root cause analysis for exception request prior to Continuous Distribution.

Dilated Cardiomyopathy

A comment received through public comment suggested removing "feeding intolerance" from the criteria satisfying the evidence of poor systemic perfusion for dilated cardiomyopathy pediatric patients under 10 kg. Initially, this criterion was included by the Workgroup in order to keep the bar from being set too high for these candidates who may qualify for 1A exception.

A Workgroup member commented that this criterion as written is vague. A member suggested clarifying feeding intolerance by including that the candidate must be total parenteral nutrition (TPN) dependent. Adding the qualification of being TPN dependent would be more specific and set the bar a bit higher.

The Workgroup member commented that inability to tolerate full enteral caloric requirement, as this criterion is described currently, is a sign of poor systemic perfusion and worsening heart failure. Workgroup members agreed that changing the description of “feeding intolerance” to include the clarification that the candidate must be TPN dependent is more clear, more concrete, and creates a higher bar. If programs have candidates that cannot tolerate TPN, they will still be able to request an exception and present their case.

A Workgroup member asked if the guidance should be more specific and include whether the candidate needs full TPN support or a combination of nutrition support including TPN. The Workgroup decided to change the criterion to “feeding intolerance requiring total parenteral nutrition.” The Chair noted that this is comprehensive enough for a guidance document. A Workgroup member commented that the two other criteria listed under the evidence of poor perfusion are less specific than the TPN requirement. The Workgroup decided to keep those criteria as written.

The Chair commented that the Workgroup has considered not including the 5 kg-10 kg dilated cardiomyopathy category in the guidance and only require that these candidates have ventricular assist devices (VADs) to be eligible for 1A exceptions. The Workgroup agreed that this category of patients need a pathway to 1A. Outcome data supports the need for less than 10 kg patients to have exception pathways outside of the use of VAD because they have higher risks with VAD support. A Workgroup member commented that there is data that shows increasing VAD volumes at a program is correlated with better outcomes. The Chair noted that children under 10 kg with VADs have higher stroke risks and higher morbidities. These smaller patients may be best managed through use of inotropes and exception requests rather than exposing them to potential risks associated with VADs when placed in smaller patients.

The Chair asked if the Workgroup is concerned that creating a pathway for exception for 5-10 kg patients who are not on VADs may interfere with similar sized patients who are on VADs at the same status. A Workgroup member commented that the patient on the VAD is stabilized and may be at the same medical urgency as the one without. The Workgroup decided to keep the 5-10 kg category in the guidance.

A Workgroup member commented that there should be some information included in the exception request that indicates whether the patient’s condition has improved due to the escalation of inotropes or if they experienced a failure to wean in order to provide evidence that inotrope support is required rather than administered to increase status. A Workgroup member questioned if this level of detail is too specific for guidance. The Workgroup decided to add “supported by one of the following with either escalation from lower dosage or a failure to wean from listed dose” to the dilated cardiomyopathy table. The Workgroup also decided to add a request for more details about inotrope escalation and failure to wean in the “Standard Information for Inclusion With Pediatric Heart Exception Requests” section.

A Workgroup member commented that 0.5 mcg/kg/min milrinone is a moderate dose but is consistent with how single high dose inotropes are defined standard listing criteria for both pediatric and adult. The Workgroup considered raising the dosing but decided to keep it as is to be consistent with the definition of single high dose inotropes included in the standard listing criteria policy.

A Workgroup member agreed with the public comment received suggesting the removal of arrhythmias from the list of contraindications to VADs. Other Workgroup members agreed. The Chair commented that patients experiencing arrhythmias may be good candidates for VADs. The Workgroup agreed to remove this criterion.

The Workgroup decided to remove content from the proposal that relates to VADs being places with the intent of increasing the patient’s status. The goal is to transplant 5-10 kg cardiomyopathy patients before they require a VAD to avoid risks and mortality associated with VADs in these smaller patients.

Coronary Allograft Vasculopathy (CAV) and Retransplant

In response to a public comment received about providing clarity regarding hospital requirements for CAV and Retransplant patients, the Workgroup decided to add language stating that hospital admission is required to be eligible for Status 1A.

In response to a public comment received suggesting the removal of triple vessel disease as a criterion, the Workgroup decided to keep it as it is one of multiple criteria.

The Workgroup discussed the comment about the guidance incentivizing programs to measure hemodynamics under suboptimal conditions in order to qualify for an exception. Unless hospitalized, this category allows a pathway for Status 1B which was deemed appropriate as these patients have a higher risk of sudden death.

The Workgroup decided to add the statement clarifying the hospital admission requirement but leave the rest of this category as written.

Single Ventricle

The Chair agrees with Fontan patients having a pathway to Status 1B. By the time these candidates may meet the standard criteria for a higher status, they may be too sick to transplant which is why this pathway is appropriate. The Workgroup agreed to keep this criteria the same. A Workgroup member commented that this 1B pathway is reasonable when also considering that these candidates have a smaller donor pool.

The Workgroup discussed the rationale behind specifically calling out Fontan patients in the Single Ventricle category. A Workgroup member asked if patients who have undergone a Norwood or Glenn procedure but may not be able to advance to a Fontan should be included in this category as well. The Chair commented that Fontan patients were specifically included because these pediatric patients were receiving higher status listing as adults. When palliation fails at a stage prior to a Fontan, patients are often more responsive to inotropes and may access higher statuses. When Fontan procedures fail, there is a smaller window for transplant. The Workgroup decided that Fontan patients should continue to be included in the guidance.

Restrictive and Hypertrophic Cardiomyopathy

The Workgroup discussed if this section would be strengthened by including a timeframe for episodes of sudden death, arrhythmia, or syncopal events as suggested by a commenter. The Workgroup decided to not include a timeframe as part of the criteria but rather request this information be included in the exception request.

A timeline will be requested in the “Standard Information for Inclusion With Pediatric Heart Exception Requests” section.

Feedback Questions

The public comments received supported not including sensitization measures in determining whether CAV candidates should be considered for 1A by exception.

Next steps:

An edited version including these changes will be sent to the Workgroup for their review and feedback.

Upcoming Meeting

- October 27, 2020

Attendance

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