OPTN Pediatric Heart Workgroup
Meeting Minutes
October 22, 2019
Conference Call

Ryan Davies, MD, Chair

Introduction

The Pediatric Heart Workgroup met via Citrix GoTo teleconference on 10/22/2019 to discuss the following agenda items:

1. Review Draft Guidance
2. Review draft review board operational guidelines

The following is a summary of the Workgroup's discussion

1. Review Draft Guidance

The Workgroup reviewed potential draft guidance for addressing the increase in status 1A pediatric exceptions.

Summary of discussion:

The Chair opened discussion as to what other potential guidance the Workgroup should draft. One Workgroup member recommended including guidance for pediatric candidates at risk of sudden death. This member also suggested that they look into restrictive cardiomyopathy candidates, because many of these patients have pulmonary vascular resistance (PVR) and arrhythmias. By doing so, the group agreed that they need to provide more guidance to identify candidate that really should be status 1A. One of these candidate groups the group identified were infants and children under the age of 1. There was concern that these candidates are competing against candidates listed for congenital heart diseases at status 1A. The workgroup agreed that infants and those under 1 year should be given a higher priority above other candidates (except those infants that are not on inotropes). Other guidance considerations that the Workgroup suggested was whether the infant candidate was on CPAP, BiPAP, and continuous feedings. If the infant has a combination of these factors, then the Workgroup agreed these infants need to be transplanted as soon as possible via status 1A exception. Other members noted that most infants who were transplanted were better off without a VAD, and these infants with VADs had to wait longer because only waitlist mortality is considered in Status 1A. The Workgroup requested data showing the waitlist morality for status 1A infants stratified by their criteria for listing. The reasoning for this request was that if the mortality rate for infants on VADs was high, but the cardiomyopathy candidates have a lower mortality rate, then perhaps they should be status 1B.

The Workgroup agreed that there are many ethical arguments when creating guidance on these issues, and that the group should be trying to maximize outcomes for the whole population. One member commented that the Workgroup should be honest, and say that surgeons want to transplant a pediatric candidate when they have a probable positive outcome. Other members noted that teens have a greater access to hearts (both pediatric and adult hearts). For example, a member stated that they have seen adolescent cases get transplanted really quickly since October 2018. For this member it almost feels like they're scheduling adolescents for VADs and then they are getting a transplant within a week of listing. Members agreed that older children need some evidence of biventricular failure or support

because this indicates a higher mortality risk. In general, older children do better with VADs, but the Workgroup was conscious not to push transplant centers towards placing VADs in children if those children do not need one.

In terms of pediatric candidates with coronary allograft vasculopathy, there is much variation in treatment amongst centers. Also, adult candidates with this condition were not taken into account with the recent policy changes back in October 2018 due to time constraints. Though the members agreed that these candidates should also be status 1A exceptions, they decided that a literature search should be conducted prior to any guidance development.

To begin drafting a guidance document for hypertrophic/restrictive pediatrics candidates, members agreed that they will utilize the current guidance document for adult hypertrophic/restrictive cardiomyopathy exception requests and tweak it for pediatrics. This document will be sent to all the Workgroup members for review and feedback.

Next steps:

Workgroup members will conduct background research for coronary allograft vasculopathy and will begin working on a skeleton draft of the guidance documents.

2. Review draft review board operational guidelines

The Workgroup reviewed potential operational guidelines for a national pediatric heart review board.

Summary of discussion:

The Workgroup agreed that the overall goal of a National pediatric heart review board (NPHRB) should be to achieve more uniformity when reviewing pediatric exception cases. Workgroup member identified cons of the NPHRB, including losing the impartiality of adult reviewers, and challenges facing random groupings. On the other side, the pros of a NPHRB include only having pediatric specialists review exception cases, and the likelihood for decreased variability. Plus, Workgroup members agreed that since the number of pediatric exception cases are fairly small, then it would be best to maintain pediatric only experts on the NPHRB.

The Workgroup members agreed that the Chair of the NPHRB should be utilized for more administrative purposes (such as breaking ties), and that the Thoracic Chair would appoint someone from the NPHRB. In terms of the review board selections, some Workgroup members advocated for no alternative representative due to the low number of pediatric thoracic heart specialists in the country. Furthermore, the alternate may become less essential because of the randomness during the selection process. On the otherhand, other Workgroup members disagreed, and stated that having random groups may result in very similar status 1As being approved and others not approved (though this may happen, having robust guidance documents may decrease this likelihood). A suggestion was to enlarge the review group to 5 or 6 persons, which may increase consistency.

Another Workgroup member stated that the reviews don't take too long and that giving longer than a week to review is excessive and that people will forget. This member advocated for 3 days (reps must vote within 3 days) and that reminders should be sent at 1 day and 2 days. Others agreed, and stated that if a reviewer fails to report within 3 days, then that case would be given another 3 days post-reassignment if not enough responses received.

Next Steps:

Workgroup members will continue their discussion of the NPHRB operational guidelines on their next call.

Upcoming Meeting

- November 26, 2019