OPTN Heart Transplantation Committee Pediatric ABOi Offers Workgroup Meeting Summary March 31, 2022 Conference Call

Brian Feingold, MD, MS, FAAP, Co-Chair Rocky Daly, MD, Co-Chair

Introduction

The Pediatric ABOi Offers Workgroup met via Citrix GoToMeeting teleconference on 3/31/2022 to discuss the following agenda items:

- 1. Brief project recap
- 2. Review Results of Data Request
- 3. Consider potential policy modifications

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

1. Project Purpose

This purpose of this project is considering modifications to *Policy 6.6.B: Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Hearts.* The goal of this modification is to align policy with current research findings relating to ABOi pediatric heart transplant and increase donor heart utilization.

2. Review Results of Data Request

The Co-Chairs discussed the primary research results from the UNOS Research data request.

Data summary:

Summary of Registrations by Willingness to Accept ABOi Offer

- Approximately 69% of candidates <1 and 18% of candidates ages 1-2 are willing to accept an ABOi heart at listing
- Percent of candidates willing to accept an ABOi heart has remained fairly consistent over time
- 35% of Status 1A candidates and 16% of Status 1B candidates were willing to accept an ABOi heart
- 5% of status 2 candidates indicated willing to accept ABOi heart (no system insurances against status 2 candidates clicking this)

Summary of Transplants by ABOi

- 12% of Status 1A transplants and 4.2% of Status 1B transplants were ABOi
- There was very little variability in percent of ABOi transplant by donor and recipient region
- The largest group of ABOi transplants was between blood type A donors and blood type O recipients
- ABOi hearts were slightly more likely to travel > 500 NM

Summary of discussion:

When reviewing the data for those not willing to accept an ABOi heart, a member noted that it is unclear how many are unwilling to aaccept because they have not been offered versus because they do not currently meet the criteria. A co-chair agreed that the data does not provide the reason why centers are unwilling to accept, but hypothesized on reasons that could lead to a program being unwilling. A member noted positive outcomes for patients over age two with negative isohemagglutinin, but emphasized the importance of being conservative on the availability of ABOi hearts for older ages until there is more long-term outcome data. The group agreed that the purpose of this proposal was not to suggest controversial titer levels, but instead use the available data to maximize the hearts available to these candidates. While discussing the data, members noted that center practices are limited due to the current policy.

3. Consider Potential Policy Modifications

UNOS staff reviewed the current relevant policies and classification tables within policy.

Summary of discussion:

First Consideration: No Policy Changes Impacting ABOi Heart Candidates Less Than 1 Year Old

One of the Chairs asked the group if they all agreed with leaving the policy as it is, which would allow every offer to be primary for those individuals. A member added that this would allow the centers to decide which titers they felt appropriate for their patient, but would still have to report what titers they decided on. The group took a voice vote and no objected with this decision.

Second Consideration: Prioritize Pediatric Heart Candidates with Low Isohemagglutinin Titer?

Workgroup members were asked to consider, should low-titer pediatric candidates be prioritized for transplant? If yes, what is the appropriate titer cut-off? These considerations are for pediatric candidates between 12 months and 18 years old.

A member noted that if the most important component is the titer number, then it would make the most sense to expand the age range, adding that a teenager with a low titer may do better with an ABOi heart transplant than an infant with a 1:16 titer. One of the Chairs highlighted that by increasing the titers, more donors will be diverted to these patients which may lead to pushback in the community. Thus, it was suggested to keep the titer low for this group and review the data after implementation to consider future titer increases. A member noted that based on the data provided, there are very few patients who fall into this age group with 1:8 or 1:16 titers so either titer cut-off would not greatly impact adult access. Members discussed the potential willingness for centers to list patients with higher titers but without the data, they would not want to make many assumptions.

Members agreed, by voice vote, to on modifying OPTN Policy 6.6.B: Eligibility for Intended Blood Group Incompatible Offers for Deceased Donors to apply for pediatric candidates ages 12 months to 18 years old.

Third Consideration: Options for Addressing Pediatric Heart Candidates with Isohemagglutinin Titer ≥ 1:16

Both options would apply to candidates who are at least one year old and less than 18 years old and who are listed for ABOi transplant with titer \geq 1:16. Members reviewed the data for heart transplants where the donors were pediatric and adult by match classification number. The purpose of this is to consider where to add the incompatible pediatric candidates in the allocation table and how it would affect patients down the match run.

Option 1: ABOi as Secondary Blood Type Candidate

Members discussed this option but were not in favor of moving forward with it. Members did not want these candidates to receive offers ahead of Status 2 pediatric patients who were a compatible match. The group did not feel comfortable with prioritizing these patients as secondary blood type candidates until they was more data available.

Option 2: ABOi as Tertiary Blood Type Candidate

When discussing pediatric donor data, members questioned whether these candidates would be more appropriately placed after adult status 3 or 4, taking into consideration the potential pushback that they could receive from adult heart programs. A member suggested placing them after status 5 adults to mitigate any potential resistance to the policy. A member countered that the data showed that 69% of pediatric donors went to pediatric recipients and encouraged the group not to be too inclusive of adult allocation for this population. A member added that they did not expect much pushback from the adult population when it comes to how to best allocate pediatric hearts. After refocusing the discussion on pediatric donors, the group agreed that slotting the ABOi tertiary candidate after adult status 3 would be appropriate.

When discussing transplants where the donor was an adult, a member expressed concern for adult status 5 multi-organ patients and suggested slotting the pediatric candidates after status 5. A member responded that often times multi-organ patients will be listed at a higher status to reflect medical urgency. The member also referenced the multi-organ transplant (MOT) policy for heart-kidney that is currently proposed, noting that other policies are being developed for these patients.

The group consensus was to proceed with option two for both pediatric and adult donors when allocating to pediatric status 1A patients.

Next steps:

The workgroup still needs to decide what the cutoff will be for low and high titers. The group also needs to decide where to allocate status 1B and status 2 ABOi recipients.

Upcoming Meetings

May 4, 2022

Attendance

Workgroup Members

- o Brian Feingold
- o Fawwaz Shaw
- o JD Menteer
- o Johanna Mishra
- o Rocky Daly
- o Shellie Mason
- o Warren Zuckerman

• HRSA Representatives

- o Jim Bowman
- o Marilyn Levi
- o Raelene Skerda
- SRTR Staff
 - o Katie Audette
 - o Yoon Son Ahn
- UNOS Staff
 - o Eric Messick
 - o Janis Rosenberg
 - o Jesse Howell
 - o Keighly Bradbrook
 - o Laura Schmitt
 - o Rebecca Brookman
 - o Sara Rose Wells