OPTN Heart Transplantation Committee
Pediatric Heart Workgroup for ABOi Offers
Meeting Summary
July 28, 2021
Conference Call

Introduction

The Pediatric Heart Workgroup for ABOi Offers (Workgroup) met via Citrix GoToMeeting teleconference on 07/28/2021 to discuss the following agenda items:

1. Review proposed options to change current allocation classifications and consider whether proposed changes have potential to disadvantage groups of candidates

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

1. Review proposed options to change current allocation classifications and consider whether proposed changes have potential to disadvantage groups of candidates

UNOS staff reviewed that the purpose of this project is to update *Policy 6.6.B: Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Hearts* to better align with current research findings relating to ABO-incompatible (ABOi) pediatric heart transplant to increase the donor pool and reduce wait time for eligible candidates. The members considered multiple options for modifying this policy.

Summary of discussion:

A member reviewed *Table 6-4: Blood Type Matching Prioritization for Heart Allocation* under *Policy 6.6.A Allocation of Hearts by Blood Type.* He noted that under 12 months of age, a candidate is assigned equal priority for all hearts, regardless of blood type. Between the ages of 12 months to 2 years, if the candidate has a titer less than or equal to 1:16 at the time of the match run, they are eligible for an ABOi transplant but allocation is still stratified and prioritized by blood type. ABOi transplants are not currently permitted for pediatric candidates who are 2 years and older.

A member shared that they believe that the cut off of 12 months of age for candidates being assigned matches regardless of blood type may be due to this population's higher mortality rate. He commented that the higher mortality rate could be due to the patient's small size, lack of similar sized donors, limited ventricular assist device (VAD) support options, as well as the severity of their congenital heart disease (CHD) diagnosis. He asked if other members agree that 12 months is the appropriate cut off. A member agreed that 12 months is an appropriate age cut off.

A member proposed allowing ABOi transplants stratified on isohemagglutinin titer for candidates ages 12 months to 2 years at the time of the match run. He also proposed allowing ABOi transplants stratified on isohemagglutinin titer for candidates ages 2 to 18 years at time of registration. He noted that the focus of this proposal should not include adults, except for adults who have received a prior ABOi transplant.

A member proposed defining a low isohemagglutinin titer as less than or equal to 1:8. Candidates that would fall into this category would include individuals who naturally lack isohemagglutinins as well as prior ABOi heart transplant recipients in need of retransplantation who did not develop anti-donor blood group isohemagglutinin antibodies. He commented that the candidates described would be a very

small percentage of candidates listed for heart transplants. The member also commented that there will need to be more consideration around ensuring that the titer reported is truly reflective of the candidate's biology and has not been impacted by any antibody depletion therapy the candidate may have received prior to drawing a sample.

Low isohemagglutinin titer (≤1:8)

The members reviewed a table proposing blood group matching prioritization for pediatric candidates 12 months to 18 years of age who are listed for ABOi heart transplants and have a titer of less than or equal to 1:8. He recommended leaving the current policy as is for O donors since they are universal donors and therefore are compatible with all recipients. Additionally, expanding the candidates listed as primary blood type candidates to all blood types for O donors has the potential to disadvantage O candidates.

A member asked if there should be additional age tiers (e.g., 4-8 years old) that have varying definitions of a low titer. Members commented that there may not be data to guide the development of additional age tiers. Another member commented that adding additional age tiers would make the schema even more complicated than it already is. A member commented that analysis after a year or two of any policy change implemented will be critical to monitor outcomes and make future adjustments as necessary.

A member questioned if an older candidate with a lower titer may have a higher propensity to produce antibodies when exposed to antigens whereas younger patients may have less ability to produce antibodies and if this would have an impact of graft survival. A member recommended consulting Dr. Lori West about biology considerations.

The members asked if Dr. Lori West could be invited to a Workgroup meeting as a guest subject matter expert. UNOS staff confirmed that she could be invited to a future meeting. A member volunteered to reach out to her with questions from the Workgroup members.

Isohemagglutinin titer ≥1:16

Option #1

The members reviewed a table proposing blood group matching prioritization for pediatric heart transplant candidates who are between the ages of 12 months and 18 years and have a titer greater than or equal to 1:16. With the exception of O donors, ABOi candidates with a titer ≥1:16 would access ABOi donors after ABO compatible (ABOc) candidates at same allocation classification and ABOi candidates with titer ≥1:16 would access ABOi donors ahead of ABOc candidates at later allocation classifications. In this proposed option, these ABOi candidates would be placed as secondary blood type candidates.

Option #2

The members reviewed a table proposing blood group matching prioritization for pediatric heart transplant candidates who are between the ages of 12 months and 18 years and have a titer greater than or equal to 1:16 in which the ABOi blood types are placed as tertiary blood type candidates. Creating a tertiary blood type group would allow for existing policy to remain intact but add another category of candidate to the allocation schema. The Workgroup would then need to decide where this category should fit into the classification table. A member agreed that this is a good approach.

A member commented that this proposed option may potentially disadvantage smaller transplant programs as larger programs may be more willing to be aggressive with ABOi transplants.

A member asked if Scientific Registry of Transplant Recipients (SRTR) modelling could be used to guide where the proposed tertiary blood group could be placed that would result in decreased waitlist mortality for the pediatric candidates. This modelling could also be used to evaluate the potential impact on adult heart transplant candidates. UNOS Research staff commented that they have been in communication with SRTR about potentially modelling. She commented that the small sample sizes available may limit the usefulness of any modelling on this patient population and asked the members what OPTN data may help support this project. A member requested the percentage of candidates that are transplanted at each status as well as the waitlist mortality. UNOS Research staff agreed to compile metrics she believed would be helpful to the Workgroup from what was discussed.

A member raised a concern that changing policy may also change behavior if it becomes advantageous to list candidates across ABO barriers. He commented that it took the U.S. a very long time to accept that ABOi transplants in infants were of equal benefit to ABOc transplants. He commented that he is concerned that there is not enough evidence to determine that ABOi transplant is no longer an issue.

A member requested the adult heart status criteria. UNOS staff provided a resource that outlines the eligibility criteria for each adult status. A member shared that adult statuses 1, 2, and 3 are roughly equivalent to pediatric Status 1A, adult statuses 4 and 5 are roughly equivalent to pediatric Status 1B, and adult Status 6 is similar to pediatric Status 2.

Next steps:

UNOS staff encouraged members to send feedback and comments about what was proposed during the meeting.

Upcoming Meeting

- TBD

Attendance

- **Workgroup Members**
  - Adam Schneider
  - Brian Feingold
  - J.D. Menteer
  - Johanna Mishra
  - Joseph P. Hillenburg
  - Melissa McQueen
  - Richard Daly
  - Shellie Mason
  - Warren Zuckerman
  - William Dreyer
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Katie Audette
  - Monica Colvin
  - Yoon Son Ahn
- **UNOS Staff**
  - Chris Reilly
  - Eric Messick
  - Keighly Bradbrook
  - Matt Cafarella
  - Rebecca Brookman
  - Sara Rose Wells
  - Sarah Konigsburg
  - Susan Tlusty