OPTN Organ Procurement and Transplantation Network

Meeting Summary

OPTN Heart Transplantation Committee
Pediatric Heart Workgroup for ABOi Offers
Meeting Summary
September 17, 2021
Conference Call

Richard Daly, MD, Chair
Brian Feingold, MD, Vice Chair

Introduction

The Pediatric Heart Workgroup for ABOi Offers met via Citrix GoToMeeting teleconference on 09/17/2021 to discuss the following agenda items:

1. Review Draft Data Request

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

1. Review Draft Data Request

UNOS Research developed a draft data request to assist the Workgroup with determining the priority that should be given to this new group of candidates willing to accept ABOi offers. The primary goal of today's meeting was for the Workgroup members to review the proposed analysis and offer feedback as to how well the proposed analysis achieves the group's objective.

Summary of discussion:

Overview of Analysis

The Vice-chair provided a summary of the project objectives and an overview of the Workgroup's activities to date. The draft data request aims to assist the Workgroup in identifying the most appropriate way to slot patients under a new framework and better understand the impact of slotting candidates in a lower priority classification row. Particularly, those patients who would be getting an ABO incompatible transplant under the non-traditional scope of what has been done previously—meaning a non-low isohemagglutinin titer ABO incompatible transplant, and where those types of candidates might belong in the Heart classification tables.

The draft data analysis is intended to provide information about the number of ABOi transplants that have been done historically and at what ages. The analysis is also intended to provide information about where pediatric transplants are happening with respect to the classification sequences. For example, if the analysis finds that the ABOi transplants are occurring within the first three sequences of the donor classification tables, either adult donors or pediatric donors, then slotting these candidates farther down will have different implications than if they are spread out throughout the allocation sequence.

Analysis Details

UNOS Research staff shared the draft data request with the Workgroup members and reminded them that the request is shared with HRSA. Overall, the data request focuses on: waitlist additions, transplants, and then more advanced metrics.

The analysis first considers pediatric waitlist additions by willingness to accept an ABOi transplant. For the purposes of this analysis, "willingness to accept an ABOi at transplant" means if the program was

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ever willing to accept an ABOi transplant on the candidate's behalf because UNet℠ contains a flag for it that can be turned on or off. The intent is to obtain an understanding about the willingness of candidates at different age groups to accept an ABOi transplant. These groups consist of candidates who are less than 1-year old, and 1-year old to 2-years old. The analysis would also do this for the group of candidates who are older than 2-years old, to verify that transplant programs had not accidentally indicated in UNet℠ a willingness to accept such offers. The analysis of those older than 2-years old will provide the Workgroup with information about how frequently that accidently occurs, and with that information in hand, that group of candidates can be eliminated from any future analyses.

Performing the analysis by year could also indicate whether the willingness to accept ABOi transplants has increased over time, and by different age groups. This could also be reviewed based on the different Heart medical urgency statuses.

For pediatric heart transplants, the analysis will look at several criteria, including medical urgency status. The analysis will break out groups of pediatric heart transplant recipients between recipients who received an ABOi transplant, an ABO compatible (ABOc) transplant, and then all together as shown as the sum of the previous two groups. The groups will be categorized using medical urgency status by classification number. To clarify, this represents the blocking classification, which is different than the allocation sequence. The breakout would be by donors at least 18 years old, as well as less than 18 years old. In addition, the following analyses will also be included: recipient blood type, classification number and recipient blood type, classification number and recipient age group, just age group, and different regions. These breakdowns will provide an overview of what is happening.

A Committee member asked for clarification regarding a "classification number." UNOS Research staff explained that classification numbers represent the priority given to certain candidates as reflected in Heart policy by *Table 6-7: Allocation of Hearts from Deceased Donors At Least 18 Years Old*, and *Table 6-8: Allocation of Hearts from Donors Less Than 18 Years Old*. For example, in Table 6-7, Classification 1 is represented by the row identifying candidates who are "Adult status 1 or pediatric status 1A and primary blood type match with the donor" and within 500 nautical miles of the donor. By comparison, the allocation sequence number shows all of the candidates within each classification number ordered by waiting time.

This approach is intended to provide the Workgroup with information for determining how to appropriately slot a new group of candidates or tertiary blood type group. For example, how to slot a group between Classification 1 and Classification 2 under current policy, the analysis would indicate approximately what percent of candidates have been in Classification 1 versus Classification 2 during the last three years, and would also provide an indication of which candidates would move up or down in terms of priority versus other groups.

The ability to analyze the set of additional metrics is dependent to some extent on having a sufficient sample size. Typically, when analyzing the pediatric population it can be challenging to determine whether sufficient sample sizes exist until the analyses are performed. If the sample sizes are sufficient, then the analysis will consider median time to transplant by willingness to accept an ABOi transplant, and medical urgency status. For example, the analysis will provide information indicating whether median time to transplant is shorter for candidates who are willing to an ABOi transplant.

Transplant rates will also be presented by medical urgency status, which is closely related to median time to transplant. Transplant rates can also be analyzed by recipient age, so recipients who are less than one-year old, or those who are one-year old to two-years old for candidates who are willing to accept an ABOi transplant. Transplant rates can also be analyzed by recipient age within the medical urgency statuses.

Finally, the analysis includes a review of offer rates, by a willingness to accept an ABOi transplant and medical urgency status. This information should provide an indication about the extent to which these candidates are getting offers and/or the changes they might expect following any potential policy changes.

The Workgroup members were asked to discuss the recipient and donor age groups that should be used for the analysis. The age of the recipients is up to two-years old, but the age of the donor can be much higher. The Workgroup's consensus was to use the age categories most often used in the OPTN benchmarking reports. The Workgroup also clarified that whether a candidate was considered pediatric or adult should be based on how the candidate was classified on the waiting list at the time of listing. For example, someone who is listed as a pediatric candidate, regardless of their age at that time of the match run, would still be considered as a pediatric candidate.

The Workgroup members also discussed whether to include OPTN region or the specific transplant program as units of analysis. A Workgroup member said there are certain areas of the country where ABOi transplants are not occurring, and programs in those areas might be impacted in the Workgroup proposed expanding the use of ABOi transplants.

Time Period of Analysis

The Workgroup members discussed the appropriate time period for analysis because both pediatric and adult heart allocation policies have experienced substantial changes during the last five years. For example, changes to pediatric heart policy were implemented in March and July of 2016. Changes to adult heart policy were implemented in September and October of 2018. Additionally, policy changes were implemented in January 2020 eliminating the use of Donation Service Areas (DSA) as an allocation criterion.

The Vice-chair stated that knowing the impact of the proposed changes on the current heart allocation system is probably going to be a more meaningful metric to the adult heart community. And, it will be important for that segment of the community to be comfortable with the impacts associated with where the Workgroup determines it is most appropriate to slot the pediatric candidates (the non-low titer candidates) being considered by this project.

UNOS Research staff said that the analysis can be performed on the data starting with October 2018 to now, and also from January 2020 to now.

Next steps:

UNOS Research staff will finalize the data request for analyzing OPTN data associated with pediatric and adult heart candidates and recipients. The finalized request will be submitted to the Workgroup's Chair and Vice-chair for approval. If approved, UNOS Research staff will begin the analysis phase.

Upcoming Meeting

- To be determined

Attendance

- **Workgroup Members**
    - Richard Daly, MD, Workgroup Chair
    - Brian Feingold, MD, Workgroup Vice-chair
    - J. D. Menteer
    - Adam Schneider
    - Johanna Mishra
    - Warren Zuckerman
- **HRSA Representatives**
    - James Bowman
    - Raelene Skerda
- **SRTR Staff**
    - Katherine Audette
- **UNOS Staff**
    - Nicole Benjamin
    - Keighly Bradbrook
    - Rebecca Brookman
    - Matt Cafarella
    - Eric Messick
    - Chris Reilly
    - Leah Slife
    - Susan Tlusty
    - Sara Rose Wells