

Meeting Summary

OPTN Heart Transplantation Committee

Heart – Pediatric Committees Workgroup – ABOi Offers Project

Meeting Summary

May 4, 2022

Conference Call

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

Introduction

The Heart – Pediatric Committee Workgroup – ABOi Offers Project met via Citrix GoToMeeting teleconference on 05/04/2021 to discuss the following agenda items:

1. Review proposed policy modifications

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

1. Review Proposed Policy Modifications

UNOS staff reviewed the proposed policy modifications and the workgroup made final decisions on how to proceed on the policy eligibility.

Summary of discussion:

A member inquired if a patient who received an ABOi heart transplant as a pediatric candidate and needed a retransplant, would be eligible for an ABOi transplant as a retransplant. The Chair responded that there was a consensus to proceed with just expanding the pediatric eligibility at this time and use that data to inform potential future changes to adult eligibility. It is possible that they will receive feedback on this during public comment and get a better understanding of what the community sentiment is toward ABOi transplants for adults.

Members discussed the titer cut offs and a member inquired why the titer was changed to 1:8 for pediatric candidates less than two years old. This decision was made as a matter of consistency throughout the policy, but members noted that there is not a clear standard for testing and want to ensure patient safety.

A member inquired about the time frame restrictions for titer reduction treatments, inquiring if 30 days was a sufficient cut off or if there should be a longer time requirement since last titer reduction treatment. The member expressed concern for the potential for gaming, but noted that nothing will fully eliminate that potential. A member added that 30 days provides the option to explore titer reduction strategies while not limiting overall patient access, but was open to expanding it beyond 30 days. Another member countered that the time frame could be 90 days or even as far as 6 months. Members clarified that titer reduction therapies would only be an option for pediatric candidates who are over one year old. A member suggested including this questions in public comment and modifying it after the fact. UNOS staff responded that increasing the time frame, as opposed to decreasing it, would require a large localization of feedback to change after public comment. Alternatively, it would be easier to reduce the time frame after public comment. Members discussed whether 30, 60, or 90 days would be the best option and ultimately decided on 30 days, which is a continuation of the existing policy requirement.

The Chair suggested more prescriptive language to identify specific antibody rejection treatments, but added that this would require ongoing review to ensure that the policy remains relevant to practice. A member countered that if a transplant center were to proceed with an ABOi transplant with mislead titers then they would be required to accept that risk of a potential bad outcome, negative impact on their patient, and retransplant. The group agreed that changes in titer that would cause a reduction in their titer would indicate titer reduction therapies.

A member inquired about the requirement to draw blood and test titers every 30 days. A member noted that it may not be convenient for the status 2 patient who is not hospitalized to meet this requirement, but this information is essential in order to make the delineation between low and high titer. A member noted that blood work could be done in an outpatient setting to be more accessible for patients who are not hospitalized. Since the policy is expanding eligibility to status 2, the workgroup felt this was an appropriate extra measure to take to ensure the titer levels in order to remain eligible for ABOi offers. If a patient does not wish to come in for an extra blood draw, they would remain on the transplant list and no longer be eligible for an ABOi offer until their titers are updated. A member suggested having those individuals who do not have an updated blood work to be placed at the tertiary blood match until they have received an updated bloodwork to qualify for secondary.

A member suggested including an example of titer interpretation into the policy. Alternatively, the transplant center education and help documentation could provide this clarification.

The group discussed the slotting for classification Table 6-8: Allocation of Hearts from Donors Less Than 18 Years Old. The group discussed whether the first classification, 'Pediatric status 1A and tertiary blood type match with the donor' then 'Pediatric status 1B and tertiary blood type match with the donor' at 1000 NM, should be at classification row 8 or 13. The group considered the data depicting what percentage of organ offers have been accepted at each row to aid in their decision. The group agreed that pediatric donors ought to be prioritized for pediatric recipients, especially after the most medically urgent primary blood type adults have received an offer, and ultimately decided to slot the first classification at row 8.

The workgroup agreed on slotting the 'Pediatric status 2 and tertiary blood type match with the donor' for 250 NM after classification row 26. The workgroup agreed on slotting 'Pediatric status 1A and tertiary blood type match with the donor' then 'Pediatric status 1B and tertiary blood type match with the donor' at 1000NM after 36. The group agreed with placing 'Pediatric status 2 and tertiary blood type match with the donor' at 500 NM after 44. 'Pediatric status 2 and tertiary blood type match with the donor' at 1000 NM will be slotted after 48. The workgroup agreed to repeat the pattern for the rest of the classification list, especially given the percentage of transplants completed at that level.

The group discussed the slotting for classification Table 6-7: Allocation of Hearts from Deceased Donors At Least 18 Years Old. The workgroup agreed to start the first classification for 'Pediatric status 1A and tertiary blood type match with the donor' at 500 NM and 'Pediatric status 1B and tertiary blood type match with the donor' at 250 NM. Due to time constraints, the group stopped here and will continue the classification slotting at their next workgroup meeting.

Next steps:

UNOS staff will schedule another meeting to finish slotting the pediatric candidates on classification Table 6-7: Allocation of Hearts from Deceased Donors At Least 18 Years Old and review the final policy language.

Upcoming Meeting

• May 10, 2022

Attendance

• Committee Members

- o Adam Schneider
- Brian Feingold
- o Fawwaz Shaw
- o JD Menteer
- o Johanna Mishra
- o Joseph Hillenburg
- o Kristin Cuff
- o Rocky Daly
- o Shellie Mason
- o Warren Zuckerman
- o William Dryer

• HRSA Representatives

o Jim Bowman

SRTR Staff

- o Grace Lyden
- o Katie Audette
- o Yoon Son Ahn

UNOS Staff

- o Eric Messick
- o Janis Rosenberg
- o Keighly Bradbrook
- o Laura Schmitt
- o Matt Cafarella
- o Rebecca Brookman
- Susan Tlusty

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