OPTN Heart Transplantation Committee
Heart – Pediatric Committees Workgroup – ABOi Offers Project
Meeting Summary
September 9, 2022
Conference Call

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Introduction

The Heart – Pediatric Committee Workgroup – ABOi Offers Project met via Citrix GoToMeeting teleconference on 09/09/2022 to discuss the following agenda items:

1. Review and Discuss Revisions to Proposed Policy Modifications

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

1. Review and Discuss Revisions to Proposed Policy Modifications

The workgroup received a brief recap of the Final Rule issues that were identified during June 2022 that delayed the proposal from moving forward with August 2022 public comment as planned. The workgroup reviewed three potential revisions to the proposed policy language. The new timeline is to proceed with public comment in January 2023.

Summary of discussion:

Recap of Final Rule issues and discussions

After hearing the Final Rule compliance concerns, members provided a variety of suggestions to remedy the concern. First, a member suggested removing the tertiary blood group to ameliorate concerns of Final Rule compliance. Additionally, the group considered either expanding the titers to 1:16 across all blood types or continuing to pursue the primary, secondary, and tertiary tiers. Additionally, a member opined that increasing the age should not be a controversial change to this policy.

A member shared the experiences of Canada and the UK in transplanting ABOi pediatric candidates. In Canada, transplant programs primarily pursue ABOi transplants in patients 5 years old and under in practice, which is a larger age range than the existing OPTN policy. In the UK, their titer policies expand titers to 1:32 and 1:64, which is higher than the current OPTN policy.

Potential revisions to proposed policy language

A workgroup member said that, ultimately, the goal is to expand access to donor hearts for pediatric candidates and to increase the number of transplants they receive, and as a result, the Workgroup should focus on how this policy revision can accomplish that goal. Another member emphasized the ability of this proposal to increase donor heart utilization and reduce pediatric organ discards. The member suggested adding data on utilization and discard rates to the proposal. A member suggested analyzing the number of low titer pediatric transplants that were done, in centers that currently do ABOi pediatric transplants, to help predict the number of patients that may be impacted by this modification. Members agreed that this information may help alleviate some concerns that there is not sufficient

OPTN data to support the change, noting that the OPTN cannot collect such data due to the current policy.

For reference, current policy establishes the following eligibity requirements for intended blood group incompatible donor heart offers:

- Candidates who are less than one-year old at the time of the match run, are registered as status 1A or 1B, and have reported isohemagglutinin titer information for A or B blood type antigens to the OPTN within the last 30 days
- Candidates who are at least one year old at the time of the match run, were registered on the waiting list prior to turning two-years old, are registered as status 1A or 1B, and have reported isohemagglutinin titers less than or equal to 1:16 for A or B blood type antigens to the OPTN from a sample collected within the last 30 days

The Workgroup reviewed three potential alternatives to the proposed policy language that they had agreed to submit to the Heart Committee in June 2022. All three alternatives would expand eligibility for ABOi heart offers to pediatric status 2 candidates. The Workgroup had originally proposed the inclusion of status 2 candidates as part of their June 2022 changes. The alternatives also reflect the Workgroup's original intention to maintain the existing eligibility criteria for candidates who are less than one-year old at the time of the match run. Such candidates would continue being classified as primary blood type match candidates.

More detailed descriptions of the proposed changes unique to each alternative are provided in the following sections.

Option 1

Option 1 largely reflected the proposed policy the Workgroup agreed to submit to the Heart Committee in June 2022. Candidates who are at least one-year old and less than 18 years old at the time of the match run who report isohemagglutinin titers of less than or equal to 1:16 would be classified as secondary blood type match candidates. This alternative would create a new blood type match classification known as "tertiary." Candidates in this age group who report titers greater than 1:16 would be classified as tertiary blood type match candidates. Candidates who report titers of less than or equal to 1:16 within the last 30 days, and who received antibody reduction therapy during that time would also be classified as tertiary blood type match candidates.

A co-Chair discussed the Final Rulse-related questions raised by internal staff that a tertiary blood group would disadvantage the patients who would be classified as 'tertiary' blood type match under the proposed policy changes. This approach surprised the member, who expected that criticism of the proposal would come from the adult heart community and focus on the potential reduction of donor hearts for adult candidates. The member was not expecting criticism of the categories chosen for pediatric candidates due to the fact that the proposal was increasing eligibility to candidates who are less than 18 years old.

Option 2

Option 2 was most similar to current policy. The primary change proposed under this option expands the eligibility age to candidates who are at least one-year old and less than 18-years old at the time of the match run. The option maintains the existing titer cut-off requirement of 1:16 and classifies such candidates as secondary blood type match candidates. There is no tertiary classification included as part of this option.

Members discussed Option 2 favorably, ultimately agreeing on pursuing this path for policy revision. The group agreed that adding a titer cut-off would provide a guardrail for ABOi transplants to be expanded, which would help to elicit community support. A member suggested that pushback for this revision could arise from the adult heart community when adult donors could be allocated to a teenage pediatric patient for an ABOi transplant ahead of an adult candidate. A member added that maintaining the 1:16 titer cut-off would be consistent with current policy and build credibility in the community. The group came to the consensus that this would be the best policy option and decided against adding additional guardrails as an attempt to mitigate negative feedback in public comment.

Option 3

The third option is similar to the second, except that there is no titer restriction imposed on candidates who are at least one-year old and less than 18-years old at the time of the match run. Such candidates are classified as secondary blood type match candidates. There is no tertiary classification included as part of this option.

A member voiced support for Option 3, noting that center practice will be so heavily dictated by their outcomes that guardrails such as titer cut-offs and tertiary blood types could be unnecessary. A member echoed this sentiment, adding that it would allow transplant centers to develop their own policies and gradually loosen the reigns as more data is available after implementation and successful transplantation. These members did express some concern about a center being very cavalier in their listing practice and listing someone that the workgroup did not think to be a safe candidate for ABOi transplant.

Members questioned if removing titers and allowing all pediatric patients to be secondary blood types would be too drastic of a step for the community to accept. The group agreed that a gradual expansion of the current policy would be more appropriate and likely to garner community buy in and support. A member added that Option 3 may be how ABOi policy evolves in the future when more data is available to inform their decisions.

General

A member wanted to know if the Workgroup could pre-emptively address the potential concerns adult heart programs might have about donor hearts being taken for older pediatric ABOi candidates. The member inquired if the Workgroup's membership included any representatives from such adult heart transplant programs who could speak to the proposed 1:16 titer cut-off, and whether its use would create concerns? However, the vast majority of Workgroup members are associated with pediatric programs. Only the Heart Committee Chair and the Heart Committee's OPO representative are involved with adult heart transplantation. The comment about prospectively considering potential criticism from adult heart programs alluded to a member opining that the strongest criticisms may have been expressed in their deliberative process. This comment alluded to the fact that the workgroup's discussions have been very robust and have greatly explored the potential feedback they could receive in public comment. Staff will review the existing questions for public comment and reconsider their relevance for the modified proposal.

Next steps:

UNOS staff will revise the policy language in accordance with the workgroup's feedback and will reach out about scheduling another workgroup meeting at the end of the month.

Upcoming Meeting

- To be determined

Attendance

- **Workgroup Members**
  - Brian Feingold
  - Fawwaz Shaw
  - Geoffrey Kurland
  - JD Menteer
  - Johanna Mishra
  - Marc Schecter
  - Rocky Daly
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Grace Lyden
- **UNOS Staff**
  - Eric Messick
  - Janis Rosenberg
  - Kelsi Linbald
  - Krissy Laurie
  - Laura Schmitt
  - Matt Cafarella
  - Susan Tlusty