Notice of OPTN Policy Changes

Expand Intended Incompatible Blood Type (ABOi) Eligibility to All Pediatric Status 1A and 1B Heart and Heart-Lung Candidates

Policies Affected:

5.3.E: Pediatric Heart Acceptance Criteria to Receive Intended Blood Group Incompatible Hearts
6.6.A: Allocation of Hearts by Blood Type
6.6.B: Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Hearts

Public Comment: January 19, 2023 – March 15, 2023
Executive Committee Approved: March 16, 2023
Effective Date: March 16, 2023

Purpose of Policy Changes

These policy changes aim to improve waiting list mortality rates by allowing status 1A and status 1B pediatric heart and heart-lung candidates registered prior to turning 18 years old access to offers from intended incompatible blood type (ABOi) donors.

Proposal History

During the January 19 – March 15, 2023 cycle, the OPTN Heart Transplantation Committee had a proposal out for public comment to expand ABOi eligibility criteria for pediatric heart, heart-lung, and lung candidates. Near the end of public comment, a transplant program contacted the OPTN about how their status 1A pediatric patient who is more than two years old could immediately qualify under the proposed policy. The OPTN reviewed the circumstances and considered options to address the program’s request in a way that is equitable for all pediatric candidates.

Executive Committee members were provided with the public comments submitted regarding the Heart Committee’s proposal. The Executive Committee met and approved the policy action on March 16, 2023. In addition to the policy changes, the Executive Committee also approved a resolution directing the Heart Committee to continue its consideration of the remaining aspects of its initial proposal and submit those aspects to the OPTN Board of Directors during the June 2023 meeting as originally anticipated.
Summary of Changes

Previously, OPTN policies allowed heart status 1A and 1B candidates who are registered on the waiting list prior to turning two years old to accept ABOi donor hearts offers. This policy change expands eligibility to receive ABOi donor heart offers to pediatric status 1A and 1B candidates who are registered before turning 18 years old. The changes also expand policy to include offers of heart-lungs.

Under the amended policy, isohemagglutinin titer values are reported for recipients of ABOi hearts who were registered on the waiting list prior to turning two years old, as opposed to previous policy, which required reporting regardless of when the pediatric candidate was registered.

Implementation

This policy was effective immediately upon OPTN Executive Committee approval. Transplant programs who wish to receive ABOi donor offers for eligible candidates should contact the Organ Center to establish a temporary, second waiting list registration for the candidate to receive ABOi heart or heart-lung organ offers. The OPTN Computer System will then appropriately include and rank the candidate in the correct sequence on subsequent deceased donor match runs, providing the qualifying candidate with ABOi offers. In addition, transplant programs will need to ensure that candidates’ blood samples are drawn at the required times and reported to the OPTN based on the requirements established in OPTN policy in order for those candidates to accept ABOi offers.

Following approval of the remainder of the proposal, anticipated in June 2023, these changes will be implemented in the OPTN Computer System, at which point the second registration will no longer be necessary.
5.3.E Pediatric Heart Acceptance Criteria to Receive Intended Incompatible Blood Group Incompatible Type Hearts

A transplant hospital may specify whether a candidate registered before two 18 years of age is willing to accept a heart or heart-lungs from an intended incompatible blood group incompatible type deceased donor.

6.6 Heart Allocation Classifications and Rankings

6.6.A Allocation of Hearts by Blood Type Matching Priority for Heart Offers

Within each classification, hearts are first allocated to primary blood type candidates then to secondary blood type candidates according to the blood type matching requirements in Table 6-4 below. Hearts are prioritized according to the blood type matching requirements in Table 6-4: Blood Type Matching Prioritization for Heart Allocation. Pediatric candidates who are eligible for intended incompatible blood type offers are prioritized according to Policy 6.6.B.ii: Blood Type Prioritization for Intended Incompatible Offers.

Table 6-4: Blood Type Matching Prioritization for Heart Allocation

<table>
<thead>
<tr>
<th>Hearts from Deceased Donors with:</th>
<th>Are Allocated to Primary Candidates defined as:</th>
<th>Then to Secondary Candidates, defined as:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Type O</td>
<td>Blood type O or blood type B</td>
<td>Blood type A or blood type AB</td>
</tr>
<tr>
<td>Blood Type A</td>
<td>Blood type A or blood type AB</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Blood Type B</td>
<td>Blood type B or blood type AB</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Blood Type AB</td>
<td>Blood type AB</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

Pediatric candidates that are less than one year old at the time of the match run, including candidates eligible to receive a heart from an intended blood group incompatible deceased donor, will be classified as a primary blood type match candidate.

Pediatric candidates that are at least one year of age at the time of the match run but registered before their second birthday and are eligible to receive a heart from an intended blood group incompatible deceased donor will be classified as a secondary blood type match candidate, unless they are a primary blood type match candidate according to Table 6-4.
6.6.B  Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Hearts

The candidate will be eligible for intended blood group incompatible heart offers if the candidate meets at least one of the following conditions:

1. Candidate is less than one year old at the time of the match run, and meets both of the following:
   a. Is registered as status 1A or 1B.
   b. Has reported isohemagglutinin titer information for A or B blood type antigens to the OPTN within the last 30 days.

2. Candidate is at least one year old at the time of the match run, and meets all of the following:
   a. Is registered prior to turning two years old.
   b. Is registered as status 1A or 1B.
   c. Has reported to the OPTN isohemagglutinin titers less than or equal to 1:16 for A or B blood type antigens from a blood sample collected within the last 30 days. The candidate must not have received treatments that may have reduced isohemagglutinin titers to 1:16 or less within 30 days of when this blood sample was collected.

Accurate isohemagglutinin titers must be reported for candidates eligible to accept an intended blood group incompatible heart according to Table 6.5 below, at all of the following times:

1. Upon initially reporting that a candidate is willing to accept an intended blood group incompatible heart.
2. Every 30 days after initially reporting that a candidate is willing to accept an intended blood group incompatible heart.

6.6.B  Intended Incompatible Blood Type Heart Offers Eligibility and Prioritization

6.6.B.i  Eligibility for Intended Incompatible Blood Type Heart Offers

Pediatric status 1A and 1B heart and pediatric heart-lung candidates are eligible for an intended incompatible blood type heart offer if all of the following conditions are met:

- The transplant program specifies the candidate is willing to accept an intended incompatible blood type heart according to Policy 5.3.E: Pediatric Heart Acceptance Criteria to Receive Intended Incompatible Blood Type Heart, and reports isohemagglutinin titer(s) information according to Table 6.5: Isohemagglutinin Titer(s) Reporting Requirements for Pediatric Candidates Willing to Receive an Intended Incompatible Blood Type Heart
- The transplant program reports updated isohemagglutinin titer information every 30 days
- And the candidate meets one of the following conditions:
  - Is less than one year old at the time of the match run
Is at least one year old at the time of the match run, and has titers less than or equal to 1:16, and has not received treatments that may have reduced isohemagglutinin titers to 1:16 or less within 30 days of when this blood sample was collected.

Table 6-5: Isohemagglutinin Titer Reporting Requirements for a Candidate Who is Willing to Receive an Intended Incompatible Blood Group-Incompatible Type Heart

<table>
<thead>
<tr>
<th>If the candidate’s blood type is:</th>
<th>Then the transplant program must report the following isohemagglutinin titers to the OPTN:</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Anti-B</td>
</tr>
<tr>
<td>B</td>
<td>Anti-A</td>
</tr>
<tr>
<td>O</td>
<td>Anti-A and Anti-B</td>
</tr>
</tbody>
</table>

6.6.B.ii Blood Type Matching Priority for Intended Incompatible Blood Type Heart Offers

An eligible pediatric status 1A or 1B heart or heart-lung candidate who is less than one year old at the time of the match run is classified as a primary blood type match candidate.

An eligible pediatric status 1A or 1B heart or heart-lung candidate who is at least one year old at the time of the match run is classified as a secondary blood type match candidate, unless they are a primary blood type match candidate according to Table 6-4.

6.6.B.iii Reporting Requirements for Recipients of Intended Incompatible Blood Type Hearts

Accurate isohemagglutinin titers must be reported for recipients of an intended incompatible blood type heart, who were registered prior to two years old according to Table 6-6, as follows:

1. At transplant from a blood sample taken within 24 hours prior to transplant.
2. If graft loss occurs within one year after transplant from the most recent blood sample, if available.
3. If recipient death occurs within one year after transplant from the most recent blood sample, if available.

Table 6-6: Isohemagglutinin Titer Reporting Requirements for a Recipient of an Intended Incompatible Blood Group-Incompatible Type Heart

<table>
<thead>
<tr>
<th>Deceased donor’s blood type:</th>
<th>Recipient’s blood type:</th>
<th>Isohemagglutinin titer reporting requirement:</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>B or O</td>
<td>Anti-A</td>
</tr>
<tr>
<td>B</td>
<td>A or O</td>
<td>Anti-B</td>
</tr>
<tr>
<td>Deceased donor’s blood type:</td>
<td>Recipient’s blood type:</td>
<td>Isohemagglutinin titer reporting requirement:</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>AB</td>
<td>A</td>
<td>Anti-B</td>
</tr>
<tr>
<td>AB</td>
<td>B</td>
<td>Anti-A</td>
</tr>
<tr>
<td>AB</td>
<td>O</td>
<td>Anti-A and Anti-B</td>
</tr>
</tbody>
</table>

If a laboratory provides more than one isohemagglutinin titer value for a tested blood sample, the transplant program must report to the OPTN the highest titer value.