

Notice of OPTN Policy Changes

Modify Heart Policy for Intended Incompatible Blood Type (ABOi) Offers to Pediatric Candidates

Sponsoring Committee:	OPTN Heart Transplantation Committee
Policies Affected:	<i>6.6.B.i: Eligibility for Intended Incompatible Blood Type Heart Offers</i> <i>6.6.B.ii: Blood Type Matching Priority for Intended Incompatible Blood Type Hearts</i> <i>6.6.B.iii: Reporting Requirements for Recipients of Intended Incompatible Blood Type Hearts</i> <i>10.4.A: Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Lungs</i>
Public Comment:	January 19, 2023 – March 18, 2023
Board Approved:	June 26, 2023
Effective Date:	Pending implementation and notice to OPTN members

Purpose of Policy Changes

These policy changes aim to improve the waiting list mortality rates of pediatric heart, heart-lung, and lung candidates by expanding eligibility to accept intended incompatible blood type (ABOi) hearts and lungs to pediatric status 2 heart and heart-lung candidates and lung candidates registered before turning 18 years old. In March 2023, the OPTN Executive Committee approved policy changes that expanded access to ABOi donor hearts and heart-lungs to candidates registered on the waiting list prior to turning 18 years old. Those changes were implemented the same day. The changes approved by the OPTN Board of Directors on June 26, 2023, will result in all pediatric heart, heart-lung, and lung candidates having access to ABOi donor organs.

Proposal History

The OPTN Heart Transplantation Committee (Committee) partnered with the OPTN Pediatric Transplantation Committee to address continued concerns that pediatric heart and heart-lung candidates do not have access to suitable donor organs. Pediatric heart and heart-lung candidates experience worse waitlist mortality rates than adult heart and heart-lung candidates. The two Committees determined to capitalize on clinical evidence from Canada and the United Kingdom indicating that older pediatric candidates are successfully transplanted using ABOi organs. As part of the Committees' efforts, it was determined that pediatric lungs candidates could also benefit from increased access to ABOi donor lungs. The OPTN Lung Transplantation Committee agreed to the proposed

changes. The Committee's proposal to expand ABOi eligibility criteria for pediatric heart, heart-lung, and lung candidates was available for public comment from January 19 – March 15, 2023.

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.

The policy changes approved by the OPTN Board of Directors on June 26, 2023, represent the remaining aspects of the initial proposal.

Summary of Changes

OPTN policies approved in March 2023 allow transplant programs to indicate they are willing to accept an ABOi donor heart and/or heart-lung for pediatric heart status 1A and 1B candidates registered on the waiting list prior to turning 18 years old. Transplant programs must report isohemagglutinin titers equal to or less than 1:16 to the OPTN every 30 days on behalf of such candidates. Previously, such candidates had to be registered prior to turning two years old. In addition, under the amended policy approved in March 2023, 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.

Under the changes approved in June 2023, eligibility to receive ABOi donor hearts, heart-lungs, and lungs was expanded to include pediatric heart status 2 candidates and lung candidates registered on the waiting lists prior to turning 18 years old. The changes also re-establish the requirement for reporting isohemagglutinin titers for recipients of ABOi donor organs regardless of when the candidate was registered.

Implementation

The policies changes approved by the OPTN Executive Committee in March 2023 were implemented immediately. Transplant programs wishing to receive ABOi donor offers for candidates eligible under the previous policies were directed to contact the Organ Center to establish a temporary, second waiting list registration. The OPTN Computer System then used the information to appropriately include and rank the candidate in the correct sequence on subsequent deceased donor match runs. Following approval of the remaining aspects of the Committee's proposal, the changes will be implemented in the OPTN Computer System, at which point the second registration will no longer be necessary. Until implementation occurs, transplant programs need to continue working with the Organ Center to establish a temporary, second waiting list registration.

Transplant programs will need to ensure that candidates' blood samples are drawn at the required times and reported to the OPTN based on the policy requirements for the candidates to accept ABOi offers.

Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

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 Type Heart

If the candidate's blood type is:	Then the transplant program must report the following isohemagglutinin titers to the OPTN:
A	Anti-B
B	Anti-A
O	Anti-A and Anti-B

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

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 Type Heart

Deceased donor's blood type:	Recipient's blood type:	Isohemagglutinin titer reporting requirement:
A	B or O	Anti-A
B	A or O	Anti-B
AB	A	Anti-B
AB	B	Anti-A
AB	O	Anti-A and Anti-B

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.

10.4.A Eligibility for Intended Incompatible Blood Group ~~Group Incompatible~~ Type Offers for Deceased Donor Lungs

Incompatible blood types are defined in *Table 10-2: Incompatible Blood Groups ~~Types~~ for Deceased Donor Lungs*.

Table 10-2: Incompatible Offers Blood Groups ~~Types~~ for Deceased Donor Lungs

Deceased Donor's Blood Type	Candidate's Blood Type
A	O and B
B	O and A
AB	O, A, and B

Candidates with incompatible blood types will be screened from lung match runs unless the candidate meets the criteria for eligibility in *Table 10-3: Eligibility for Intended Incompatible Blood Group ~~Incompatible~~ Type Offers for Deceased Donor Lungs* below.

Table 10-3: Eligibility for Intended Incompatible Blood Group Incompatible Type Offers for Deceased Donor Lungs

If the candidate is <u>registered prior to turning 18 years old</u> and is:	And meets <i>all</i> of the following:
Less than one year old at the time of the match run	1. Has a waiting list survival score of at least 1.9073 2. 1. Has reported isohemagglutinin titer information for A or B blood type antigens to the OPTN within the last 30 days
At least one year old at the time of the match run	1. Is registered prior to turning two years old 2. Has a waiting list survival score of at least 1.9073 3. 1. 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