

Notice of OPTN Policy Change

Require Notification of Critical Human Leukocyte Antigen (HLA) Typing Changes

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| Sponsoring Committee: | Histocompatibility |
| Policies Affected: | <i>4.4: Resolving Discrepant Donor and Recipient HLA Typing Results</i> <i>4.4.A: Requirement to Notify Transplant Programs and OPOs</i> <i>4.4.A.i: Donor HLA Critical Discrepancies</i> <i>4.4.A.ii: Candidate and Recipient HLA Critical Discrepancies</i> <i>4.4.B: Requirement to Resolve Critical Discrepant Donor and Recipient HLA Typing Results</i> |
| Public Comment: | January 21, 2021 – March 23, 2021 |
| Board Approved: | June 14, 2021 |
| Effective Date: | September 1, 2021 |

Purpose of Policy Change

This policy change defines what constitutes a critical human leukocyte antigen (HLA) typing change and establishes an OPTN requirement for histocompatibility laboratories and organ procurement organizations (OPOs) to communicate HLA typing changes when a candidate, recipient, or donor critical HLA typing change occurs. A lack of awareness regarding discrepant HLA typing can lead to adverse events such as hyperacute rejection, graft failure, and death.

Proposal History

The OPTN Histocompatibility Committee reviews discrepant HLA typings at least every three months, according to OPTN *Policy 4.4: Resolving Discrepant Donor and Recipient HLA Typing Results*. There have been 37 patient safety reports to the OPTN due to discrepant HLA typings between January 1, 2018 and April 1, 2021. Multiple reports specified that the transplant programs or OPOs were not contacted in a timely fashion, leading the Histocompatibility Committee to pursue a policy change to mandate notification due to its patient safety implications. The Histocompatibility Committee developed this proposal in collaboration with the OPO, Operations and Safety, and Kidney Committees to ensure consideration for logistical implications and that no candidates are disadvantaged.

Summary of Changes

The proposal sets forth requirements regarding when OPOs and histocompatibility labs need to provide notification of critical HLA typing changes. These notifications would be required any time an HLA typing is changed to a non-equivalent value at one or more loci, regardless of the cause of the change. Any

form of notification that requires acknowledgment would be acceptable, including a phone call. All notifications must be followed by documentation of the correct typing. *Figure 1: Proposed Notification Requirements* summarizes the requirements:

Figure 1: Proposed Notification Requirements for Critical HLA Discrepancies

| When member... | Does... | For... | They must notify... | Within... |
|-------------------------------|--|------------------------|---------------------|------------------------------|
| Histocompatibility laboratory | Determines correct typing | Donor | OPO | 1 hour |
| | | Candidate/Recipient | Transplant hospital | 5 days |
| OPO | Receives documentation from laboratory, or discovers independently | Donor pre-procurement | Transplant hospital | 12 hours, or pre-procurement |
| | | Donor post-procurement | Transplant hospital | 24 hours |

In response to public comment feedback, the Histocompatibility Committee changed the donor notification timeframe for post-procurement from 12 to 24 hours to mirror other post-procurement donor findings, such as post-procurement donor culture results or discovery of malignancy. The Committee also clarified language defining the discovery of the discrepancy, to state that the histocompatibility laboratory must determine the correct HLA typing prior to notification.

Implementation

Histocompatibility laboratories will need to train and ensure key personnel complete data entry for the HLA discrepancy reports. Completing the report is already a requirement under current OPTN policy. OPOs will need to train staff on the requirement to notify and provide documentation to all accepting transplant programs. Transplant hospitals will need to provide staff training on the new requirements regarding the expected notification and HLA information that will be received for reported discrepancies.

The OPTN will create educational materials to support members with the new requirements established in this proposal.

Affected Policy Language

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

4.4 ~~Resolving Critical HLA Discrepant~~ Discrepancies in Candidate, Donor, and Recipient HLA Typing Results

~~Laboratories must submit donor and recipient histocompatibility forms to the OPTN after transplant according to Policy 18: Data Submission Requirements. After laboratories submit donor and recipient HLA typing results to the OPTN, the OPTN will provide a report to the laboratories including any discrepant HLA typing results.~~

Laboratories must resolve discrepancies within 30 days of notification of discrepant HLA typing results. The Laboratory Director or designated staff must contact the other Laboratory Director or designated staff to resolve the discrepancies. Each laboratory involved in the HLA typing discrepancy must identify and report the reason for the discrepancy to the OPTN.

The OPTN will remove all discrepant flags from HLA typing results that have been resolved. Discrepancies that have not been resolved will remain flagged. The Histocompatibility Committee will review, at least every three months, any outstanding discrepant typing recorded since the last review. The committee will use the results of these reviews to determine whether policy modifications are required.

For the purposes of this policy, a human leukocyte antigen (HLA) critical discrepancy is a difference among non-equivalent values, according to *Policy 4.10: Reference Tables of HLA Antigen Values and Split Equivalences*, at one or more loci in a candidate's, donor's, or recipient's HLA typing.

4.4.A Requirement to Notify Transplant Programs and OPOs

4.4.A.i: Donor HLA Critical Discrepancies

If a laboratory becomes aware of a critical discrepancy in a deceased donor's HLA typing, the laboratory must notify the host OPO of the discrepancy. Notification and supporting documentation must be provided as soon as possible, but no later than one hour following determination of the correct HLA typing.

Upon independent discovery or receipt of documentation of the discrepancy, the OPO must do the following:

- If the discrepancy is discovered prior to procurement, the OPO must notify and provide supporting documentation to all accepting transplant programs as soon as possible, but no later than 12 hours following discovery of the discrepancy or prior to procurement, whichever occurs first.
- If the discrepancy is discovered post-procurement, the OPO must notify and provide supporting documentation to all accepting transplant programs within 24 hours following the discovery.

4.4.A.ii: Candidate and Recipient HLA Critical Discrepancies

If a laboratory discovers a critical HLA discrepancy in a candidate's or recipient's HLA typing, the laboratory must notify the listing transplant program and provide documentation of the discrepancy as soon as possible, but within 5 days following determination of the correct HLA typing.

4.4.B: Requirement to Resolve Critical Discrepant Donor and Recipient HLA Typing Results

The laboratory director of each laboratory involved in the HLA typing discrepancy, or their designee, must identify the correct HLA typing and report the reason for the discrepancy to the OPTN within 60 days of discovery of the discrepancy.

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