OPTN Policy Notice
Addressing HLA Typing Errors

Sponsoring Committee:	**Histocompatibility Committee**
Policy/Bylaws Affected:	**Policy 2.2 (OPO Responsibilities), Policy 4.3 (Requirements for Performing and Reporting HLA Typing), Policy 4.4 (Resolving Discrepant Donor and Recipient HLA Typing Results), and Bylaws C.2.D (OPO Affiliation)**
Public Comment:	**August 3 – October 3, 2018**
Effective Date:	**March 1, 2019: Policy 2.2 (OPO Responsibilities) and Bylaws C.2.D (OPO Affiliation)** **Pending Implementation and Notice to Members: Policies 4.3 (Requirements for Performing and Reporting HLA Typing) and 4.4 (Resolving Discrepant Donor and Recipient HLA Typing Results)**

Problem Statement

The OPTN does not have a system for timely reporting and reviewing human leukocyte antigen (HLA) typing errors. Because HLA typing discrepancies are flagged on the donor and recipient histocompatibility forms completed after transplant, there is no timely mechanism for detecting errors in the HLA information used for generating match runs used in organ allocation.

HLA data entry errors, specifically prior to match run generation, can have serious patient safety implications. These HLA typing errors can also create system inefficiencies.

Summary of Changes

1. When HLA data is entered manually into UNet, it must be entered twice (by the same person) for verification of accurate data entry
2. When HLA data are uploaded directly into UNet, the member must have a process for verifying that the data are accurate
3. Raw HLA typing must be attached in the system for verification of lab results

What Members Need to Do

There will be two implementation phases.

By March 1, 2019, OPOs and the labs they work with will need to have a process in place to ensure that the raw HLA data for deceased donors is uploaded in DonorNet in the source documentation section. Members that upload HLA data directly into UNet will need to ensure that they have an internal process for verifying the accuracy of HLA data outlined in the written agreement between the lab and the center they serve.

Upon notification to members, members entering HLA data into UNet will be prompted to enter the data twice. Members should be aware of this change, but will not need to make any process changes as a result of this modification.

Affected Policy Language

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

2.2 OPO Responsibilities

The host OPO is also responsible for *all* of the following:

1. Identifying potential deceased donors.
2. Providing evidence of authorization for donation.
3. Evaluating deceased donors.
4. Maintaining documentation used to exclude any patient from the imminent neurological death data definition or the eligible data definition.
5. Verifying that death is pronounced according to applicable laws.
6. Establishing and then implementing a plan to address organ donation for diverse cultures and ethnic populations.
7. Ensuring the clinical management of the deceased donor.
8. Ensuring that the necessary tissue-typing material is procured, divided, and packaged.
9. Assessing deceased donor organ quality.
10. Preserving, labeling, packaging, and transporting the organs. Labeling and packaging must be completed using the OPTN organ tracking system according to *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage*.
11. Executing the match run and using the resulting match for each deceased donor organ allocation. The previous sentence does not apply to VCA transplants; instead, members must allocate VCAs according to *Policy 12.2: VCA Allocation*.
12. Documenting and maintaining complete deceased donor information for seven years for all organs procured.
13. Ensuring that all deceased donor information, according to *Policy 2.11: Required Deceased Donor Information,* is reported to the OPTN Contractor upon receipt to enable complete and accurate evaluation of donor suitability by transplant programs.
14. Ensuring that documentation for *all* of the following deceased donor information is submitted to the OPTN Contractor upon receipt:
    a. ABO source documentation
    b. ABO subtype source documentation
    c. Infectious disease results source documentation
    d. Death pronouncement source documentation
    e. Authorization for donation source documentation
    f. HLA typing source documentation
15. Maintaining blood specimens appropriate for serologic and nucleic acid testing (NAT), as available, for each deceased donor for at least 10 years after the date of organ transplant, and ensuring these samples are available for retrospective testing. The host OPO must document the type of sample in the deceased donor medical record and, if possible, should use qualified specimens.

4.3 Requirements for Performing and Reporting HLA Typing

Laboratories must ensure that all HLA typing is accurately determined and report HLA typing results to the OPO or Transplant Program according to the ~~turnaround time~~ deadlines specified in the written agreement between the laboratory and ~~any affiliated~~ the OPO or transplant program. Laboratories must report HLA typing results to the OPTN Contractor. HLA typing results that are entered manually must be verified by reporting each result twice.

4.4 Resolving Discrepant Donor and Recipient HLA Typing Results

Laboratories must submit donor and recipient histocompatibility forms to the OPTN Contractor after transplant according to *Policy 18.0: Data Submission Requirements*. After laboratories submit donor and recipient HLA typing results to the OPTN Contractor, the OPTN Contractor will provide a report to the laboratories including any discrepant HLA typing results.

~~The report includes *all* of the following donor information:~~

1. ~~Donor id~~
2. ~~HLA typing results~~
3. ~~Date of tests~~
4. ~~Test methods~~
5. ~~Laboratory Identifiers~~
6. ~~OPO Identifier (if applicable)~~

~~The report includes *all* of the following recipient information:~~

1. ~~SSN~~
2. ~~HLA typing results~~
3. ~~Date of tests~~
4. ~~Test methods~~
5. ~~Laboratory identifier~~

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 Contractor.
The OPTN Contractor 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.

Bylaw Language:

C.2 Facilities and Resources

D. OPO Affiliation

Histocompatibility laboratories must have written agreements with every OPO member the laboratory serves, unless clinical urgency prevents such an agreement. Written agreements between histocompatibility laboratories and OPOs must include *all* of the following:

1. The sample requirements for typing and crossmatching.
2. The loci and level of resolution typed.
3. A process for requesting extended HLA typing.
4. A process for <u>verifying and</u> reporting HLA typing results to the OPTN Contractor.
5. A process for resolving HLA typing discrepancies and errors.
6. The maximum turnaround time from receipt of donor sample to reporting of results to the OPO.
7. A process for prioritizing donors for histocompatibility testing.
8. The length of time for which donor specimens are required to be stored for repeat or future testing.
9. If the OPO performs crossmatching, then all methods used for crossmatching and the interpretation and reporting of the results.