OPTN Histocompatibility Committee
Meeting Summary
May 14, 2024
Webex Meeting

John Lunz, MD, Chair
Gerald Morris, MD, Vice Chair

Introduction

The Histocompatibility Committee ("Committee") met via WebEx teleconference on 05/14/2024 to discuss the following agenda items:

1. Require Reporting of HLA Critical Discrepancies to the OPTN - Patient Safety Portal
2. Require Reporting of HLA Critical Discrepancies to the OPTN – Policy Language Review
3. Revise Policies, Bylaws, and Guidance

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

1. Require Reporting of HLA Critical Discrepancies to the OPTN – Patient Safety Portal

No decisions were made.

Presentation Summary:

The goal of the reporting proposal is to increase the recording of discrepancies and their reasons. An OPTN staff member reviewed the OPTN patient safety reporting portal discrepancy data related to histocompatibility. The staff member reviewed reports of issues in the OPTN patient safety reporting portal. Staff reviewed a subcategory of sample switches, which included lab tested wrong sample, technological error, wrong donor sample sent, and wrong recipient sample tested. Staff also reviewed a subcategory of typing discrepancies, including deviation from standard process, incorrect Bw4/6 assignment, limitations based on typing method, and low-resolution vs high resolution testing.

Summary of discussion:

OPTN staff highlighted the importance of this data to allow histocompatibility labs to create corrective action plans.

Next steps:

None.

2. Require Reporting of HLA Critical Discrepancies to the OPTN – Policy Language Review

The committee decided that 01:01 and 01:02 are not critically discrepant and that values within the same serological split antigen group within policy 4.11 table are considered equivalent. The committee decided that HLA discrepancies are defined as a difference among non-equivalent values at one or more loci in a candidate's, donor's, or recipients HLA typing. The committee decided that discrepancies should be reported to the OPTN within two business days. In policy 4.4B, language was changed from "donor critical" to "critical" regarding HLA typing.

Presentation Summary:

Policy changes were reviewed.

Summary of discussion:

Staff asked if p-group equivalents should count as critical discrepancy, where one lab reports the p-group, and another reports an allele within the p-group? Further, staff asked what the timeline should be for reporting discrepancies to the OPTN? Lastly, they asked if incorrect samples used for crossmatch should be included in required reports?

A committee member brought up the importance of consistent language and definitions for p-groups. The Vice Chair mentioned that alleles within the same p-group are equivalent according to the table, and therefore aren't considered a critical discrepancy. The committee discussed policy language changes. The Vice Chair stated that serological equivalents and p-groups are not the same, so new language clarifying this could be helpful, as current policy has these on the same side of the equivalency table. A member said that if two labs got the same serological equivalent, then they're considered equivalent, while p-groups may not be necessary in this scenario. The Vice Chair said that if only serological split-level typing is used, then the only discrepancies would be serological accuracy, while acknowledging that p-groups simplified the antigen table. Some members mentioned that this is not a high enough standard of scrutiny. Staff stated that current policy verbiage lists unacceptable antigen equivalents but should not state all HLA values on the right side of the table as equivalent.

A member asked about implications regarding allele-specific avoids. The Vice Chair said that high-resolution should not be reported unless it is true high-resolution, defined as "highest determined unambiguous resolution," while a member answered that labs should be moving towards high resolution typing. The committee decided on policy changes of critical discrepancy, equivalencies, and their definitions. The committee reviewed policy regarding requirements for HLA typing discrepancies. Staff mentioned a future policy recommendation for designating which labs (those who discovered an error or those who made an error) should report the error to the OPTN. The Vice Chair suggested that the lab who discovers an error should report it to speed up the reporting process.

The committee discussed if two business days is an acceptable limit for reporting discrepancies. A member raised concern about implications of this policy for at-risk organ recipients, and the committee decided that reporting should occur within 24 hours.

The committee discussed if incorrect samples or incorrect typing/testing for physical or virtual crossmatches should be reported. The committee agreed that this is a safety issue.

Next Step

These changes will go out for public comment.

3. Revise Policies, Bylaws, and Guidance

The committee added "process for HLA results to the OPTN" into crossmatching requirements and antibody screening. The committee changed language clarifying that a primary data coordinator only needs to be "identified" rather than a requirement of new staffing.

Presentation Summary:

Staff reviewed the background of a project to update policies/guidance to align with CLIA regulations. Staff covered a policy change to remove requirements to follow American Society for Histocompatibility and Immunogenetics and College of American Pathologists checklists, as this is duplicative language.

Language was added requiring address changes for labs to be reported to the OPTN. Staff reviewed new, clarified typing requirements. The committee added “process for HLA results to the OPTN” into crossmatching requirements and antibody screening. The committee reviewed personnel requirements, and a member raised concerns about burden of having a primary data coordinator, when for some labs this is a transplant coordinator who is not answerable to the lab. This language was changed to “identifying” a primary data coordinator rather than staffing one. The Vice Chair highlighted possible future changes for the “pathway 1” section of policy according to Centers for Medicare and Medicaid. Staff reviewed the laboratory coverage plan policy, where a committee member raised concern about laboratory coverage plans surrounding faculty members and leave notice requirements. The committee discussed use of the word “contractor” related to reporting key personnel changes.

Next Steps:

The Committee decided to hold another meeting to continue reviewing policy language.

Upcoming Meeting(s)

- May 28, 2024

Attendance

- **Committee Members**
  - Qingyong Xu
  - Caroline Alquist
  - Laurine Bow
  - Stephanie Osier
  - John Lunz
  - Julie Houp
  - Jerome Saltarrelli
  - Andres Jaramillo
  - Hermant Parekh
  - Helen McMurray
  - Gerald Morris
  - Manish Gandhi
  - Darryl Nethercot
  - Crystal Usenko
  - Amber Carriker
- **HRSA Representatives**
  - Marilyn Levi
- **SRTR Staff**
  - Katie Audette
- **UNOS Staff**
  - Thomas Dolan
  - Courtney Jett
  - Tamika Watkins
  - Susan Tlusty
  - Laura Schmitt
  - Amelia Devereaux
  - Kayla Balfour
- **Other Attendees**
  - Tiffany Bratton
  - Rajalingam Raja
  - Michael Gautreaux
  - Jon Miller