OPTN Histocompatibility Committee
Meeting Summary
May 28, 2024
Webex Meeting

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

Introduction

The Histocompatibility Committee ("Committee") met via WebEx teleconference on 05/28/2024 to discuss the following agenda items:

1. Revise Bylaws, Appendix C
2. Require Reporting of HLA Critical Discrepancies to the OPTN
3. Revise Policies and Guidance

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

1. Revise Bylaws, Appendix C

The Committee voted to send the bylaws to the Policy Oversight and Executive Committees for approval for Summer 24 public comment release.

Presentation Summary:

The group reviewed Membership and Professional Standards Committee (MPSC) feedback, in which the MPSC asked if histocompatibility lab directors should have currency requirements like those of surgeons. The presenter stated that they responded by highlighting accreditation by inspections.

OPTN Staff reviewed proposed changes:

- Allow multiple OPTN-approved laboratory directors at a histocompatibility lab
- Update laboratory director education and training requirements
- Modify required personnel and add a primary data coordinator to act as the point of contact for the OPTN
- Update laboratory subcontracting requirements
- Add inactive and withdrawal notification requirements
- Remove criteria for mandatory performance review and required information from labs with unsatisfactory performance
- Remove requirements that are redundant to other existing regulatory requirements for labs and clarify language

OPTN staff reviewed minor Appendix C language changes. This included adding clarifying language around states of exemption for CLIA (Clinical Laboratory Improvement Amendments) and removing duplicative language around facilities requirements. Staff reviewed HLA typing requirements and crossmatching requirements. Language was added to clarify that the process for reporting crossmatching results to the transplant hospital for verifications includes both physical and virtual crossmatching. For antibody screenings, language was changed to state that if desensitization is

performed, a protocol for monitoring antibody testing and reporting should be included. For OPO (Organ Procurement Organization)-affiliation, language was removed for a requirement for virtual crossmatching requirements. Personnel requirement language was added to clarify licensing standards. Staff reviewed additions to the Histocompatibility Laboratory Key Personnel requirements, where language was added specify that only one laboratory director can serve as the primary director on record with the OPTN. Language was also added that the director must fulfill responsibilities as a high-complexity director.

Summary of discussion:

For personnel requirements, the committee discussed the inclusion of volume requirements in this section. The committee did not feel that this section needed extended volume guidelines. When viewing supervisor qualifications, a committee member raised concern about the three-year minimum to hold the position. Regarding this, language was added to require experience in all of one's laboratory test types. The committee also decided to ask for public comment feedback about proposed general supervisor qualifications. A meeting guest mentioned that language discussing foreign credentials should refer to CLIA.

Laboratory coverage plan language was changed to include clinical consultants, as well as a new requirement for submission of an updated coverage plan when any key personnel accepts additional responsibilities for more than 30 days at another laboratory. This plan is listed to be submitted to the OPTN within 30 days of accepting additional responsibilities. A member stated that in the future, there should be consideration for backup plans for directors in emergent situations.

Language regarding mandatory performance review was removed for repetition. Inactive status language was removed for later changing. Language related to CLIA certification for subcontractors was removed, as well as test result reviews. Inactivation and withdrawal language was added to define the role of an inactivated facility and requirements for notices of inactivation from the laboratories. Language defining steps for a laboratory were added to withdraw OPTN membership.

Next steps:

The Bylaws proposal will be sent to the Policy Oversight and Executive Committees for approval for Summer 24 public comment release.

2. Require Reporting of HLA Critical Discrepancies to the OPTN

The Committee voted to send the bylaws to the Policy Oversight and Executive Committees for approval for Summer 24 public comment release.

Presentation Summary:

OPTN Staff reviewed goals of HLA critical discrepancies, including ensuring labs are performing root cause analysis and corrective action plans.

Summary of discussion:

Staff reviewed language changes around critical discrepancies, which are now defined as a difference between non-equivalent values at one or more loci in HLA typing. This was followed by values within the same serological split antigen group or provided as equivalent are considered equivalent. Language was added that discrepancies must be reported to the OPTN patient safety reporting portal within 24 hours of discovery, with reason for discrepancy reported within 60 days. Language around HLA unacceptable

antigen equivalencies was clarified following previous conversations. A table was added defining when reporting is required for discrepancies.

The committee decided to add additional language to the policy for resolving and reporting OPTN critical discrepant donor and recipient HLA typing results by inserting additional “donor” language into the HLA typing discrepancy guideline.

Next Step

The Bylaws proposal will be sent to the Policy Oversight and Executive Committees for approval for Summer 24 public comment release.

3. Revise Policies and Guidance

No decisions were made.

Presentation Summary:

The Chair decided to hold off on this topic until there is further guidance expected to be released related to Clinical Laboratories Improvement Act (CLIA) by the Centers for Medicaid and Medicare Services (CMS) later this year.

Next Steps:

Upcoming Meeting(s)

- June 11, 2024

Attendance

- **Committee Members**
  - Qingyong Xu
  - Laurine Bow
  - Stephanie Osier
  - John Lunz
  - Jerome Saltarrelli
  - Helen McMurray
  - Gerald Morris
  - Darryl Nethercot
  - Crystal Usenko
  - Amber Carriker
  - Omar Moussa
  - Roshini Abraham
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Katie Audette
- **UNOS Staff**
  - Thomas Dolan
  - Courtney Jett
  - Tamika Watkins
  - Susan Tlusty
  - Laura Schmitt
  - Amelia Devereaux
- **Other Attendees**
  - Tiffany Bratton (Incoming Committee Member)
  - Ryan Pena (Incoming Committee Member)