OPTN Histocompatibility Committee
Meeting Summary
October 1, 2024
In-Person Meeting

Gerald Morris, MD, Chair
Kelley Hitchman, PhD, MS, Vice Chair

Introduction

The Histocompatibility Committee ("Committee") met in-person on 10/01/2024 to discuss the following agenda items:

1. **Post-Public Comment Review and Discussion**
2. **Post-Public Comment Modifications**
3. **Update Post-Transplant Histocompatibility Data Collection**
4. **Committee Updates**

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

1. Post-Public Comment Review and Discussions: HLA Critical Discrepancies

VOTE: *Required Reporting of HLA Critical Discrepancies and Crossmatching Events to the OPTN* received unanimous support.

Summary of Presentation:

OPTN contractor staff presented post-public comment analysis to the Committee. Staff reviewed that the *Required Reporting of HLA Critical Discrepancies and Crossmatching Events to the OPTN* (HLA proposal) was received positively in most regions, with some opposition in Region 4 due to the proposal's 24-hour reporting time.

Staff reviewed the following topics:

- Time burdens
- HLA typing samples
- Staffing
- Critical discrepancy definition
- Virtual crossmatching
- Patient safety
- Additional comments

Most public comment feedback for the HLA proposal fell within "time burdens" and "critical discrepancy definition." Feedback for time burdens included that 24-hours was not an appropriate timeframe for reporting. Feedback for critical discrepancy definition included that the proposed definition was not appropriate because it did not outline both low-resolution and two-field testing.

Summary of Discussion:

The Chair clarified that the 24-hour time frame is referring to reporting as opposed to conducting a full root-cause analysis, responding to a member who said the proposed language is unclear. The Chair mentioned that currently, they have no idea how erroneous samples affect allocation, and a precise definition could clarify reporting requirements. The Committee discussed the importance of being inclusive and exacting in their policy language regarding discrepancies.

A staff member clarified that the current practice for compliance is that patient safety reports are investigated and further action, such as root cause analyses corrective action plans, and possibly others, are requested. She clarified that the 60-day window is for the OPTN Data System and patient safety reports may be more involved. The Chair also mentioned educational materials available to the histocompatibility community.

Staff moved into public comment feedback about the proposed critical discrepancy definition. The public asked for clarification on p-groups in the critical discrepancy definition.

Staff reviewed proposed changes from leadership that would change the proposal's 24-hour reporting time into 72-hours. Leadership mentioned that compliance standard is becoming 72-hours, and a change in reporting time could help align with this. The Committee discussed the importance of clarifying that this time is for reporting and follow-up could take place outside of this 72-hour window. The Chair also mentioned that aspects of the process affecting allocation, such as organ procurement organization reporting, happens sooner than the proposed 72-hours, and that the histocompatibility committee's role in this is to collect information on data collection and near-miss events. The Committee discussed the possibility of outlining discrepancy errors in the policy.

Staff moved into the critical discrepancy definition proposal change, which included mentioned of "within the same p-group according to IMGT/HLA are considered equivalent." A committee member stated that if a lab chooses to report two-field, it must be p-group reporting. The Chair stated that serologic split antigen groups should be included in the definition to help prevent false discrepancy reporting. Committee members agreed that both serologic split antigen groups and p-groups should be included in the definition. The Vice Chair suggested that two-field typing must be within the same p-group for equivalency.

Leadership proposed changes to the discovering lab reporting outline, in which they removed "HLA donor typing," replaced the language "test" with "sample," and added that virtual crossmatching should be done "per program testing agreement." They stated that this both clarified public comment concerns around confusing language and removed typing language redundancies. The Committee moved on to vote on this language.

Next steps:

None

Post-Public Comment Review and Discussions: Bylaws

VOTE: *Update Histocompatibility Bylaws* received unanimous support.

Summary of Presentation:

OPTN contractor staff reviewed public comment feedback regarding the Update Histocompatibility Bylaws Proposal. Staff presented that there was general support for the proposal, with some opposition in Region 4 about the multiple lab director requirements. Themes from public comment included:

- Support for bylaws update
- Multiple lab directors
- Collaboration with other organizations/stakeholders
- Written agreements between programs
- Other comments

Staff reported that there was mixed sentiment about requirements for multiple lab directors. The public asked for more clarification around a consistent lab director definition. Histocompatibility stakeholder American Society for Histocompatibility and Immunogenetics (ASHI) recommended deferring regulatory roles to organizations with Center for Medicare and Medicaid (CMS) deemed status. ASHI also suggested maintaining the lab director portfolio review and deferring this process to accrediting organizations. ASHI recommended against written agreements for organ procurement organization to minimize administrative burdens.

Summary of Discussion:

The Chair mentioned that the purpose of this bylaw change is to align with Clinical Laboratory Improvement Amendments (CLIA) requirements, and that histocompatibility labs have the right to stay regulated by the Membership and Professional Standards Committee (MPSC) of the OPTN. The Chair emphasized the importance of having multiple lab director eligibility options is important.

The Committee reviewed the pathway proposed language, which would align the eligibility requirements with CLIA, and the Chair stated that the CLIA eligibility would eliminate redundancy and allow more pathways to lab director eligibility. The Committee discussed language changes around role definitions for lab directors, technical supervisors, and clinical consultants. A member mentioned that this definition should be inclusive of both qualifications and responsibilities. The Committee clarified which CLIA regulations within the policy change are for qualifications and for responsibilities, respectively.

The Committee discussed compliance options for this proposal. The Vice Chair discussed case logs and their validity for portfolio reviews. The Vice Chair suggested having CLIA directors sign-off on CVs to attest to their accuracy. A member asked about clinical consulting requirements, and the Vice Chair stated that CLIA's regulations require directors to meet technical supervisor standards.

For the proposal evaluation plan, the Committee suggested 20 continuing education credits following a break in service. Requirements for serving as a lab director would also include education and licensing standards, as well as evidence of training.

Next steps:

None

2. Update Post-Transplant Histocompatibility Data Collection

No decisions were made.

Summary of Presentation:

Staff reviewed updates to OPTN Data Systems (TIEDI) forms to improve data collection. The recipient Histocompatibility Form, Donor Histocompatibility Form, and Discrepant HLA Typings Report have data collection updates. Staff reviewed mock-ups of these updated forms.

Summary of Discussion:

The Committee expressed approval of the forms and said it will relieve some data burdens.

Next steps:

None

3. Committee Updates

No decisions were made.

Summary of Presentation:

Staff reminded the Committe of the upcoming virtual crossmatching webinar. The Committee discussed new project ideas, including ABO typing requirements, re-evaluate requirements for program agreements, and requirement for key personnel renewal/recertification processes. They added that they'd also like to talk about donor typing entry data.

Next steps:

None

Upcoming Meeting

- November 12, 2024

Attendance

- **Committee Members**
  - Bobbie Rhodes-Clark
  - Crystal Usenko
  - Dave Pinelli
  - Darryl Nethercot
  - Gerald Morris
  - Helene McMurray
  - Kelley Hitchman
  - Hemant Parekh
  - John Lunz
  - Julie Houp
  - Mike Hurtik
  - Jerome Saltarelli
  - Laurine Bow
  - Michael Gautreaux
  - Ryan Pena
  - Stephanie Osier
  - Tiffany Bratton
  - Qingyong Xu
- **HRSA Representatives**
  - Marilyn Levi
  - Adriana Burton
  - Laurine Bow
- **SRTR Staff**
  - Katie Audette
- **UNOS Staff**
  - Thomas Dolan
  - Jamie Panko
  - Susan Tlusty
  - Amelia Deveraux
  - Joann White